UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO_____**

Commission File No. 001-36395

DARÉ BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-4139823**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)
3655 Nobel Drive, Suite 260 **San Diego, CA** (Address of Principal Executive Offices)	**92122** (Zip Code)

Registrant's telephone number, including area code: **(858) 926-7655**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	**Name of each exchange on which registered**
Common Stock, Par Value $0.0001 Per Share	**DARE**	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on the last business day of the registrant's most recently completed second fiscal quarter was approximately $33,967,214 based on the closing price of the registrant's common stock as reported on the Nasdaq Capital Market on such day. This excludes shares of common stock held by affiliates on such date. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power directly, or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant. The determination of affiliate status for this purpose may not be conclusive for other purposes.

As of March 28, 2025, there were 8,850,386 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2025 annual meeting of shareholders (the "2025 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2025 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Daré Bioscience, Inc. and Subsidiaries
Form 10-K – ANNUAL REPORT
For the Fiscal Year Ended December 31, 2024
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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, in particular ITEM 1. "BUSINESS," ITEM 7. "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS," and the information incorporated by reference herein contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, projected revenue, funding and expenses, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "pursue," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors described in PART I, ITEM 1A, "RISK FACTORS," in this report, and elsewhere in this report. Given these uncertainties, you should not place undue reliance on any forward-looking statement. The following factors are among those that may cause such differences:

- *Inability to raise additional capital, under favorable terms or at all, to fund our operating needs and continue as a going concern;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *The number and scope of product development programs we pursue;*
- *Difficulties or delays in commencement or completion, or the termination or suspension, of our current or planned clinical or preclinical studies;*
- *Clinical trial outcomes and results of preclinical development;*
- *Failure to complete development of our product candidates or submit and obtain United States Food and Drug Administration, or FDA, or foreign regulatory authority approval for our product candidates on projected timelines or budgets, or at all;*
- *Challenges and delays in obtaining timely supplies of our product candidates, including their components as well as the finished product, in the quantities needed in accordance with current good manufacturing practices, our specifications and other applicable requirements;*
- *The performance of third parties on which we rely to conduct nonclinical studies and clinical trials of our product candidates;*
- *Inability to enter into arrangements with outsourcing facilities on commercially reasonable terms required to compound and distribute the compounded drugs that we seek to make available under Section 503B of the Federal Food, Drug, and Cosmetic Act, or FDCA;*
- *The removal of sildenafil citrate or any other bulk drug substance needed to compound the compounded drugs that we seek to make available under Section 503B of the FDCA from the FDA's list of bulk drug substances that can be compounded under Section 503B of the FDCA;*
- *The performance of third parties on which we will rely to bring to market, or assist us in bringing to market, compounded drugs;*
- *A change in regulatory requirements related to compounded drugs under Section 503B of the FDCA;*
- *Our failure, or a failure of a strategic collaborator, to successfully commercialize our product candidates, if approved, or our failure to otherwise monetize our portfolio programs and assets;*
- *Termination by a collaborator of our respective out-license agreements for commercialization of XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO, and Ovaprene®, or, in the case of Ovaprene, a decision by the collaborator not to make the license grant fully effective following its review of the results of the ongoing pivotal clinical trial of Ovaprene;*

- *The timing and amount of future royalty, milestone or other payments to us, if any, under our out-license agreement for Ovaprene, and of upside-sharing milestone payments from XOMA under our traditional and synthetic royalty purchase agreements, if any;*
- *The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;*
- *Difficulties with maintaining existing collaborations relating to the development and/or commercialization of our product candidates, or establishing new ones on a timely basis or on acceptable terms, or at all;*
- *The terms and conditions of any future strategic collaborations relating to our product candidates;*
- *The degree of market acceptance that XACIATO and any future product achieves;*
- *Coverage and reimbursement levels for XACIATO and any future product by government health care programs, private health insurance companies and other third-party payors;*
- *Our loss of, or inability to attract, key personnel;*
- *A change in the FDA's prior determination that the Center for Devices and Radiological Health would lead the review of a premarket approval application for potential marketing approval of Ovaprene;*
- *A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b)(2) of the FDCA, or the FDA's 505(b)(2) pathway;*
- *Unfavorable differences between preliminary, interim or topline clinical study data reported by us and final study results;*
- *Communication from the FDA or another regulatory authority, including a complete response letter, that such agency does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that such agency interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *Failure to select product candidates that capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas within women's health including due to our limited financial resources;*
- *Loss or impairment of our in-licensed rights to develop and commercialize XACIATO and our product candidates;*
- *The timing and amount of our payment and other obligations under our in-license and acquisition agreements for XACIATO and our product candidates;*
- *Developments by our competitors that make XACIATO, or any potential product we develop, less competitive or obsolete;*
- *Unfavorable or unanticipated macroeconomic factors, geopolitical events or conflicts, public health emergencies, or natural disasters;*
- *Weak interest in women's health relative to other healthcare sectors from the investment community or from pharmaceutical companies and other potential development and commercialization collaborators;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems and data, our financial resources and other assets, or the technology systems and data of third parties on which we rely;*
- *Difficulty in introducing branded products in a market made up of generic products;*
- *Inability to adequately protect or enforce our, or our licensor's, intellectual property rights;*
- *Lack of patent protection for the active ingredients in XACIATO and certain of our product candidates that expose them to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*

- *Dependence on grants and other financial awards from governmental entities and private foundations to advance the development of several of our product candidates;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results or results that differ from investors' expectations for such results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could cause investors to experience losses and subject us to securities class-action litigation;*
- *Development of safety, efficacy or quality concerns related to our product or product candidates (or third-party products or product candidates that share similar characteristics or drug substances), whether or not scientifically justified, leading to delays in or discontinuation of product development, product recalls or withdrawals, diminished sales, and/or other significant negative consequences;*
- *Product liability claims or governmental investigations;*
- *Changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, pricing and/or marketing of our products, product candidates and related intellectual property, health care information and data privacy and security laws, transparency laws and fraud and abuse laws, and the enforcement thereof affecting our business; and*
- *Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.*

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

All forward-looking statements in this report are current only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as required by law.

ITEM 1. BUSINESS

The terms "we," "us," "our," "Daré" or the "Company" refer collectively to Daré Bioscience, Inc. and its wholly-owned subsidiaries, unless otherwise stated or the context otherwise requires. All information in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

Overview

We are a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority. We exist to accelerate innovation in women's health and we believe that innovation does not have to start from scratch. With growing awareness around menopause, sexual health, and vaginal health, the conversation is shifting, but access to real, evidence-based solutions still lags behind. We continuously hear from healthcare providers, researchers, and women themselves about the urgent need for access to evidence-based treatment options. Our goal is to fulfill that need by bringing to market as soon as practicable innovative evidence-based treatment solutions that address decades of unmet needs in women's health and enhance outcomes and convenience, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause - areas in women's health that we believe represent compelling and meaningful market opportunities. The solutions we aim to bring to market will primarily be available only with a physician's prescription – either as an FDA-approved product or as a compounded drug under Section 503B of the FDCA. We may also bring to market consumer health products that can be obtained without a physician's prescription.

We began assembling our diverse portfolio of assets in 2017 through acquisitions, exclusive in-licenses and other collaborations. The first FDA-approved product to emerge from our portfolio is XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe). We achieved FDA approval of XACIATO three years after acquiring rights to the program. XACIATO was approved by the FDA in December 2021 as a single-dose

prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023 and, in January 2024, Organon announced that XACIATO was available nationwide. As described below, to provide funding for the development of the product candidates in our pipeline, in April 2024, we entered into an agreement with XOMA (US) LLC, or XOMA, whereby we sold our rights to all royalty and potential milestone payments based on net sales of XACIATO under our agreement with Organon, net of our obligations to certain third parties, until XOMA receives a specified return on its investment, after which we will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon.

Our product candidates are in various stages of development, from pre-clinical through a pivotal Phase 3 clinical study. The most advanced product candidates we are developing are: Ovaprene®, an investigational, hormone-free, monthly intravaginal contraceptive currently being evaluated in a pivotal Phase 3 clinical study, whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil, the active ingredient in Viagra®, for the treatment of female sexual arousal disorder (FSAD); and DARE-HRT1, an intravaginal ring designed to deliver combination menopausal hormone therapy, bio-identical 17β-estradiol and progesterone together, continuously over a 28-day period for the treatment of moderate to severe vasomotor symptoms, also known as hot flashes.

As discussed in more detail below, because we believe women should not have to wait for needed medical treatment solutions, we are expanding our business strategy to include 503B compounding as a dual-path approach to bring some of our proprietary formulations to market as soon as practicable while we continue to pursue FDA approval of our product candidates. 503B compounding refers to the production and supply of compounded drugs by 503B-registered outsourcing facilities without patient-specific prescriptions in accordance with Section 503B of the FDCA. We are taking action to utilize 503B compounding to bring our proprietary Sildenafil Cream formulation to market, and we are targeting to make it available in the fourth quarter of 2025. In parallel, we will continue to pursue FDA approval of Sildenafil Cream as a treatment for FSAD. Bringing our proprietary Sildenafil Cream formulation to market via 503B compounding will not impact the regulatory process or commercial opportunity for an FDA-approved Sildenafil Cream product. Rather, if successful, 503B compounding will be a source of revenue from existing assets that is non-dilutive to our stockholders.

Our Strategy

Our business strategy is to in-license or otherwise acquire the rights to intellectual property and know how that enables us to develop and bring to market differentiated evidence-based solutions that we believe can address unmet needs in women's health and enhance outcomes and convenience, and that represent compelling and meaningful market opportunities. Certain assets we have in-licensed have existing clinical proof-of-concept data or an established safety profile for the active pharmaceutical ingredient that we seek to leverage. We may pursue regulatory approval of a product candidate through clinical development or, if the active pharmaceutical ingredient is on the FDA's list of bulk drug substances for which there is a clinical need, we may seek to bring it to market under Section 503B of the FDCA. In certain circumstances, as discussed in more detail below with respect to our proprietary Sildenafil Cream formulation, we may pursue both pathways. We believe having alternative pathways allows us to bring solutions to market as soon as practicable and optimizes access for women in a fiscally responsible manner.

We are primarily focused on progressing the development and achieving commercialization of our existing portfolio of product candidates. However, we also explore opportunities to expand our portfolio through both business development activities that may result in acquiring, or acquiring access to, new intellectual property rights and know how through in-licensing or other collaborative arrangements, and leveraging platform technology assets we previously acquired or in-licensed from third parties that can be modified with different active pharmaceutical ingredients to address multiple indications. As with our current portfolio, we seek innovations in women's health that have (a) attractive market opportunities with the potential to address an unmet need, including through new formulations, manners of application or delivery methods of well-known drug substances that result in novel product candidates customized for women, (b) human proof-of-concept clinical data previously generated by third parties, (c) potential to utilize the FDA's 505(b)(2) pathway, and/or (d) potential to become a first-in-category or first-line product. We consider a candidate to have potential to become a "first-in-category" product when we believe that, if the candidate were to successfully complete clinical development and receive marketing approval for the use for which it is being developed, or for which we anticipate developing it, the product would address a need in women's health that is not being met by existing FDA-approved products.

Key elements of our business strategy are as follows:

- *Accelerate innovation in women's health and bring our proprietary formulations and other assets to market as soon as practicable utilizing all available pathways for the asset*, including as a compounded drug under Section 503B of the FDCA, as an FDA-approved product, or as a consumer health product that does not require a physician's prescription.
- *Advance clinical development of the product candidates in our portfolio through mid- to late-stage clinical development or regulatory approval*. In 2024, we continued to make important progress in the clinical development of our product candidates, including with ongoing enrollment in the pivotal Phase 3 study of Ovaprene.
- *Explore opportunities to expand our portfolio, with evidence-based solutions for women's health as our sole focus*. While simultaneously advancing our current portfolio, we intend to continue to identify other important areas of unmet need in women's health and to explore opportunities to build our portfolio by acquiring or in-licensing new programs or leveraging assets we previously acquired or in-licensed to create new programs that meet our selection criteria.
- *Pursue strategic collaborations to fund our business, enhance our development and commercialization capabilities, and/or commercial offerings, optimizing for access in a fiscally responsible manner.* With respect to our product candidates, we intend to develop and maintain strategic relationships with commercial-stage companies that are leaders or emerging leaders in women's health, as well as with other entities, where we believe such collaborations will help fund our business or accelerate or otherwise improve upon our clinical development and regulatory strengths and/or product manufacturing, and commercialization capabilities. With respect to 503B compounding, we intend to develop and maintain relationships with Section 503B-registered outsourcing facilities to help bring our proprietary formulations to market. Examples of strategic collaborations to date include our license agreement with Organon to commercialize XACIATO, and our license agreement with Bayer to commercialize Ovaprene, if approved and the license becomes effective.
- *Seek non-dilutive sources of funding to support product development.* We intend to advance development of our product candidates through a variety of means, including through non-dilutive funding and potential revenue from 503B compounding. To date, we have received non-dilutive

funding from federal government agencies and/or a private foundation to support various aspects of our research and development activities, from preclinical discovery to a Phase 3 clinical study, for eight of our programs. We intend to continue to explore grants and other forms of non-dilutive funding to support development of our product candidates.

XACIATO™

XACIATO (clindamycin phosphate) vaginal gel, a lincosamide antibacterial, received FDA approval in December 2021 for the treatment of bacterial vaginosis in female patients 12 years of age and older.

XACIATO is our first and, to date, only approved product. We achieved FDA approval of XACIATO three years after acquiring rights to the program. We commenced and completed a successful pivotal clinical study, prepared and filed a new drug application, or NDA, with the FDA and received notification from the FDA of U.S. marketing approval, all during the COVID-19 pandemic.

In 2022, we licensed to Organon exclusive worldwide rights to develop, manufacture and commercialize XACIATO. See "Strategic Agreements for Product Commercialization" below for further discussion of the terms of our agreement with Organon. We remained the NDA holder of XACIATO until December 2023, at which time the NDA was transferred by the FDA to Organon, and Organon assumed all manufacturing responsibilities, regulatory and compliance matters. Organon is also responsible for commercializing, promoting, determining pricing, and negotiating reimbursement matters related to XACIATO. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023, and, in January 2024, announced that XACIATO was available nationwide. As described below, to provide funding for the development of the product candidates in our pipeline, in April 2024, we sold to XOMA our rights to all royalty and potential milestone payments based on net sales of XACIATO under our agreement with Organon, net of our obligations to certain third parties, until XOMA receives a specified return on its investment, after which we will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon. See below under "Royalty Monetization Transactions" for additional details.

XACIATO previously received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis in women. As a result of the QIDP designation, XACIATO was eligible to receive a five-year extension of the three years of data exclusivity in the U.S. available to the product based on the submission of new clinical data that were essential to its approval. The FDA granted XACIATO for the treatment of bacterial vaginosis in female patients 12 years of age and older three years of data exclusivity, which was extended by five years, such that the data exclusivity period will expire on December 7, 2029. XACIATO has also been designated as a reference listed drug by the FDA for purposes of future generic drug development. The data exclusivity period should block the FDA from approving either a subsequent abbreviated NDA or 505(b)(2) NDA that relies in whole or in part on our protected clinical data. See also "Government Regulation - U.S. Government Regulation- New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension" below. Additionally, see the discussion of patents and patent applications related to XACIATO under "Intellectual Property—Patents" below.

Our Pipeline: Clinical-Stage Programs

Ovaprene®

We believe the need for more effective and convenient options is particularly true with contraception. While a variety of hormonal and non-hormonal options exist, there is a notable void: an effective, short-acting, hormone-free method of contraception that does not require intervention at the time of intercourse.

Ovaprene is a novel, investigational hormone-free monthly intravaginal contraceptive designed to be worn conveniently over multiple weeks (one menstrual cycle) that currently is being evaluated in a pivotal Phase 3 clinical study. Based on the results of our pre-pivotal postcoital test, or PCT, clinical trial, as discussed below, we believe Ovaprene has the potential to achieve “typical use” contraceptive efficacy in the range of approximately 86% to 91% at 6-months, which approaches the approximately 93% typical use efficacy at 12-months of current FDA-approved non-implanted, non-injected hormonal contraceptive methods (pills, patches and vaginal rings). Typical use contraceptive efficacy refers to the expected rate of pregnancy prevention during the first year of actual use of a method, including sometimes using the method in a way that is not correct or not consistent. Ovaprene features a proprietary knitted polymer barrier to physically block sperm from entering the cervical canal within a silicone-reinforced ring that releases non-hormonal agent ferrous gluconate to impede sperm motility. Unlike current FDA-approved monthly intravaginal contraceptives, Ovaprene does not contain hormones, but, consistent with those monthly intravaginal contraceptives, including Merck’s NuvaRing®, Ovaprene is designed to be a “one size fits most”

monthly, self-administered product. If approved, Ovaprene could be the first hormone-free, monthly contraceptive option for women.

Ovaprene is composed of both device and drug components and is considered a combination product by the FDA. There is no predicate device for Ovaprene (i.e., there is no existing FDA-approved product that the FDA can use to compare with Ovaprene). As such, Ovaprene will be reviewed via a premarket approval, or PMA, process and not a 510(k) premarket submission. While the regulatory process for such a novel product can require more interactions and research to support FDA approval, the benefit is a clearly differentiated product. Ovaprene previously underwent a request for designation process with the FDA that determined that the Center for Devices and Radiological Health, or CDRH, would lead the review of a PMA application for potential marketing approval in the U.S.

Clinical Data

In a PCT pilot clinical study conducted by the previous sponsor in 20 women and published in *The Journal of Reproductive Medicine*® in 2009, Ovaprene demonstrated the ability to immobilize sperm and prevent their progression into the cervical mucus. The study also demonstrated the acceptability of the device to both partners. No colposcopic abnormalities, no significant changes in vaginal flora and no serious adverse effects were observed.

In November 2019, we announced positive topline results of our PCT clinical trial of Ovaprene (ClinicalTrials.gov ID: NCT03598088). We designed the PCT clinical trial to assess general safety and effectiveness in preventing progressively motile sperm from reaching the cervical canal following intercourse and acceptability of the product to the patient. The study evaluated 23 women over the course of five menstrual cycles, with each woman assessed over approximately 21 visits. Each woman's cervical mucus was measured at several points during the study, including a baseline measurement at menstrual cycle 1 that excluded the use of any product. Subsequent cycles and visits included the use of a diaphragm during intercourse (menstrual cycle 2) and Ovaprene (menstrual cycles 3, 4 and 5). The primary endpoint of the study was to evaluate changes from baseline in PCT results due to device use, as represented by the proportion of women and cycles with an average of fewer than five progressively motile sperm (PMS) per high power field (HPF) in midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.

Our PCT clinical trial met its primary endpoint: Ovaprene prevented the requisite number of sperm from reaching the cervix across all women and all cycles evaluated. Specifically, in 100% of women and cycles, an average of less than five PMS per HPF were present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place. To calculate the average number of PMS, PMS were counted across each of nine HPFs and averaged. Women enrolled in the study who completed at least one Ovaprene PCT (N=26) had a mean of 27.21 PMS/HPF in their baseline cycle when no contraception was used, a mean of 0.22 PMS/HPF in their diaphragm cycle, which was anticipated based on published studies, and a mean of 0.48 PMS/HPF in their Ovaprene PCT cycles, with a median of zero PMS. No serious or severe adverse events were reported or observed.

Ovaprene use did not result in cervicovaginal irritation or adverse effects on resident vaginal microbiota, and did not impact transitions from a Lactobacillus-dominated community state type to an anaerobic, diverse vaginal microbiota community state type IV. Use of Ovaprene resulted in meeting the prespecified criterion for contraceptive effect by all participants during all postcoital test cycles. The safety and PCT results from this study were published in the peer-reviewed journal Contraception, an international reproductive health journal and the official journal of the Society for Family Planning.

PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness. Infertility research suggests that higher rates of pregnancy are associated with PMS per HPF of from greater than one to greater than 20 PMS, and less than five PMS per HPF is considered indicative of contraceptive effectiveness. In a peer-reviewed article published in the journal *Biology of Reproduction* that analyzed the use of PCT studies in the development of vaginal contraceptives, the authors observed, for instance, that Lea's Shield and the Ortho and Caya diaphragms had 0 PMS/HPF in their respective PCT studies and six-month typical use failure rates in contraceptive effectiveness trials of 8.7, 7.9, and 12.5%, respectively. The article concluded that, although ultimate contraceptive efficacy is influenced by the ease and convenience of use of a product, along with patient compliance, a PCT study of a test product can be predictive of contraceptive effectiveness, and PCT results similar to results seen with products such as Lea's Shield and the Ortho and Caya diaphragms is the best indicator of likely success of the test product in a contraceptive effectiveness study.

Pivotal Phase 3 Clinical Study

In December 2023, we announced commencement of the multi-center, single arm, non-comparative, pivotal Phase 3 clinical study of Ovaprene to evaluate its effectiveness as a contraceptive along with its safety and acceptability (ClinicalTrials.gov ID: NCT06127199). The study aims to enroll sufficient participants across approximately 20 study sites in the U.S. to have approximately 250 participants complete approximately 12 months (13 menstrual cycles) of use. Based on typical dropout rates for contraceptive efficacy studies, we will seek to enroll more than double the number of subjects we target to complete 13 menstrual cycles of use. Twenty clinical research sites from within the Eunice Kennedy Shriver National Institute of Child Health and Human Development's (NICHD) Contraceptive Clinical Trials Network (CCTN) were trained on the protocol and were initiated to start screening and enrolling participants in late 2023 and early 2024. Currently, there are 15 active NICHD CCTN sites following enrolled participants in the study. Enrollment is currently proceeding at five study sites that were initiated in 2025, funded by a grant we received in 2024 from the Gates Foundation, or the Foundation, to accelerate the overall study timeline. We anticipate that approximately 125 women, which is half of our target number of participants to complete the study, will complete approximately six months of Ovaprene use by the end of the second quarter of 2025. This is a designated check point for review of interim data by the study's data safety monitoring board, or DSMB, an independent group of experts which evaluates the safety and integrity of the study.

The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. If successful, we expect the study to support the submission of a premarket approval application for Ovaprene to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

The Phase 3 study is being conducted, in part, under our Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services (HHS), as represented by the NICHD, part of the U.S. National Institutes of Health (NIH), and within the CCTN. Under the CRADA, we and NICHD each provide medical oversight and final data review and analysis for the study at these sites and will work together to prepare the final report of the results of the study from these sites. We are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million to NICHD to be applied toward the costs of conducting the Phase 3 study, all of which had been paid as of September 30, 2024. NICHD is responsible for the other costs related to the conduct of the Phase 3 study and for managing the payment of expenses to the contract research organization for the study, the clinical sites, and other parties involved with the study. Executive orders and other actions taken by the new U.S. presidential administration in the first quarter of 2025 have negatively impacted the Phase 3 study and NICHD's ability to carry out its responsibilities under the CRADA. In particular, the NICHD process to enter into contract modifications with the CCTN sites participating in the study in the same manner as it would ordinarily do to provide additional funding to those sites within the current budget under the CRADA has been impacted and remains uncertain. As a result, to help ensure the CCTN sites remain active for continued follow-up with existing study participants, we and NICHD agreed to pause recruitment of new participants at the CCTN sites. This pause in recruitment at the CCTN sites does not effect the anticipated timing for reaching the designated check point for DSMB review. Depending on its duration, it could adversely impact the overall enrollment rate for the study and increase the time and cost to us to complete the study. In addition, most of the CCTN sites participating in the study are part of colleges or universities, and the federal government recently has terminated or threatened to terminate grants and contracts with colleges and universities, including clinical study contracts with at least one university that is a CCTN site in our study. To date, these developments have not materially impacted the study, however, if NICHD is unable to enter into new contracts or contract modifications with CCTN sites for a prolonged period, or terminates its contracts with CCTN sites in our study before the study follow-up visits with existing participants are completed or before the study is completed, we may determine to contract directly with those sites to enable them to restart recruitment and enrollment of new participants and/or ensure they remain active sites to continue follow-up with existing participants, which could increase the time and cost to us to complete the study. There is a high level of uncertainty relating to U.S. government contracts and funding and regulation of research and development, as well as the functioning and funding of many federal government departments and agencies in general, and future developments may significantly delay or jeopardize the completion of the Phase 3 study and significantly increase the cost of the study to us. Further, depending on the duration of the enrollment period and number of subjects enrolled in the Phase 3 study, there may be future costs associated with the study that are not reflected in the current budget under the CRADA for the CCTN sites. We and NICHD have been in discussions regarding the CRADA, which are continuing and which may include discussing a mechanism to potentially provide for additional future payments by us in support of the Phase 3 study for the CCTN sites to complete subjects already enrolled, in the event that the currently budgeted CRADA funds are insufficient. As discussed above, we have contracted directly with five new study sites, which began recruiting in the

first quarter of 2025, with the support of grant funding we received from the Foundation. At this time, due to the uncertainty regarding the CCTN sites and because the five new study sites only recently began participant recruitment, we cannot reasonably predict the enrollment rate for the remainder of the study or an estimated time for completion of enrollment.

We are collaborating with ADVA-Tec, Inc., or ADVA-Tec, and Bayer HealthCare LLC, or Bayer, for the development and commercialization of Ovaprene as part of two strategic collaborations announced in March 2017 and January 2020, respectively. See "Strategic Agreements for Pipeline Development" and "Strategic Agreements for Product Commercialization" below for discussion of the terms of each collaboration.

Sildenafil Cream, 3.6%

While numerous pharmaceutical products have been developed and approved to treat erectile dysfunction (ED) in men, women continue to lack effective options for female sexual arousal disorder, or FSAD, which is clinically analogous to ED in men. To date, there are no FDA-approved pharmacological treatments for FSAD. Market research conducted in 2015 suggests that approximately 33% of women in the U.S. ages 21 to 60 are not satisfied with their sexual arousal, and half of those women, 16% of women in the U.S. ages 21 to 60, or approximately 10 million women, are distressed from experiencing symptoms associated with FSAD, including lack of or low sexual arousal, and are actively seeking solutions to improve their condition. In comparison, the prevalence of complete ED in men is estimated to be about 5% of men at age 40, increasing to about 15% at age 70. We are developing Sildenafil Cream, 3.6%, or Sildenafil Cream, an investigational proprietary cream formulation of sildenafil, a phosphodiesterase-5 inhibitor and the active ingredient in the male erectile dysfunction drug Viagra®, for topical administration to the female genitalia for treatment of FSAD. Because, today, there are no treatments approved by the FDA for FSAD, there are no efficacy endpoints that have been previously validated in a Phase 3 pivotal study for potential treatments for FSAD. Our Phase 2b RESPOND clinical study of Sildenafil Cream, which is discussed below, was a first of its kind Phase 2b clinical study that included patient reported outcome (PRO) instruments to screen eligible women and a number of primary, secondary, and exploratory PRO assessments to measure improvement in localized genital sensations of arousal and reduction in the distress that women experience with FSAD. The study enabled us to identify a subgroup of patients who are most likely to benefit from Sildenafil Cream therapy and achieve meaningful improvement in their symptoms.

Based on data from the Phase 2b RESPOND study and feedback from the FDA, we are preparing to advance Sildenafil Cream into a Phase 3 clinical study for the treatment of FSAD. A second confirmatory Phase 3 study will be required to support an NDA submission. We plan to leverage the existing data and established safety profile of sildenafil and the Viagra® brand to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of Sildenafil Cream in the U.S. for the treatment of women suffering from FSAD. If approved, Sildenafil Cream could be the first FDA-approved FSAD treatment option for women.

FSAD, as described in the Diagnostic and Statistical Manual of Mental Disorders 4th Edition Text Revision ("DSM IV TR"), is a condition characterized primarily by a persistent or recurrent inability to attain or maintain sufficient genital arousal (an adequate lubrication-swelling response) during sexual activity, frequently resulting in distress or interpersonal difficulty. This is distinct from hypoactive sexual desire disorder (HSDD) in women (also described in DSM IV TR), which is characterized primarily by lack or absence of sexual fantasies and desire for sexual activity (also commonly referred to as low libido). As with erectile dysfunction in men, FSAD in women is associated with insufficient blood flow to the genitalia. Sildenafil Cream is designed to facilitate vasodilation and increase genital blood flow, and, as a result, to provide improvements in the female genital arousal response, while avoiding systemic side effects observed with oral formulations of sildenafil.

Clinical Data

In a Phase 1 clinical study conducted by our licensor Strategic Science and Technologies, LLC, or SST, of three escalating doses of topical sildenafil cream (1 g cream with 35 mg sildenafil; 2 g cream with 71 mg sildenafil; and 4 g cream with 142 mg sildenafil) in 20 healthy postmenopausal women using a crossover study design, topical sildenafil cream demonstrated significantly lower systemic exposure to sildenafil compared to a 50 mg oral sildenafil dose, and topical sildenafil cream was well tolerated at clinically relevant doses (1-2 g cream). Study subjects reported favorable product characteristics: easy to use and readily absorbed.

In a Phase 2a, single center, single-dose, double-blind, placebo-controlled, 2-way crossover study conducted by SST, women with FSAD, ages 21 to 60, received a single 2 g dose of Sildenafil Cream. Of the 35 women enrolled, 31 (15 premenopausal and 16 postmenopausal) completed the study. The primary objective was to evaluate the efficacy of Sildenafil Cream compared to placebo cream assessed by participant-reported levels of subjective

cognitive sexual arousal and by physiological genital arousal response. Sildenafil Cream demonstrated increases in measurable blood flow to the genital tissue compared to placebo (mean change in vaginal pulse amplitude analysis) using a vaginal photoplethysmograph approximately 30 minutes post-dosing. Treatment with a single dose of 2 grams of Sildenafil Cream (71 mg sildenafil) applied intravaginally and externally to the labia minora and clitoris in study participants was well tolerated. No serious adverse events (SAEs) were reported. A total of 18 treatment emergent adverse events (TEAEs) were reported, with a similar incidence under Sildenafil Cream treatment (8 events in 4 participants [12.1%]) and under placebo treatment (10 events in 4 participants [12.1%]). The majority of these TEAEs were considered to be related to treatment (14 out of 18). All TEAEs were all mild or moderate in severity; in particular, TEAEs reported under Sildenafil Cream treatment were all mild. Half of the 18 TEAEs reported were in the system organ classification of "Reproductive system and breast disorders", and events included vaginismus, vulvovaginal burning sensation, vulvovaginal discomfort, and vulvovaginal pain. There were more of these TEAEs under Sildenafil Cream treatment than under placebo (6 and 3, respectively). However, these events were typically transient (lasting less than 1 minute) and resolved without medical attention.

A Phase 1, single-dose, double-blind, placebo-controlled, two-way crossover study to evaluate the feasibility of using thermography to assess the pharmacodynamics (PD) of Sildenafil Cream in normal healthy women was conducted at a single center. During the thermography study, genital temperature, a surrogate for genital blood flow, was captured and recorded utilizing an infrared camera capable of detecting heat patterns from blood flow in body tissues. The study, which was designed to evaluate up to 10 subjects, achieved the study objectives based on a planned interim analysis of the first six completed subjects, and thus additional subjects were not enrolled. In this study, Sildenafil Cream demonstrated significantly greater increases in genital temperature compared to placebo cream, indicating a positive impact on genital blood flow during the 30-minute post-dosing testing session, with statistical separation from placebo cream within the first 15 minutes after dosing. Additionally, significantly greater self-reported arousal responses were reported during Sildenafil Cream visits compared to placebo cream visits. One postmenopausal subject had a mild vaginal burning sensation following application of both the placebo cream and Sildenafil Cream, which resolved itself and did not require any additional intervention or study withdrawal. One subject had a small laceration to the perineum post coitus, which was unrelated to study treatment and participation, resolved itself, and did not require additional intervention or withdrawal.

In 2019, as part of our exploratory Phase 2b clinical program for Sildenafil Cream, we completed a non-interventional study, or the content validity study, designed to identify and document the genital arousal symptoms that are most important and relevant to women with FSAD. Participants who met the eligibility criteria participated in one-on-one, in-depth interviews conducted by subject matter experts in the field of clinical outcome assessments and female sexual medicine. The findings of that study helped facilitate alignment with the FDA on acceptable efficacy endpoints in our exploratory Phase 2b clinical study and future Phase 3 program, including with respect to the patient reported outcome, or PRO, instruments to be used to screen eligible patients with FSAD and to measure achievement of the primary efficacy endpoint in the Phase 2b study.

In April 2023, we initiated subject enrollment in a Phase 1, single-dose, double-blind, placebo-controlled, 3-way crossover clinical study of Sildenafil Cream using thermography to assess the PD and pharmacokinetic (PK) characterization of Sildenafil Cream. The study was closed in March 2024. Sildenafil Cream was well tolerated in the study. Among the 13 enrolled participants, two subjects had a mild vaginal burning sensation following application of Sildenafil Cream and placebo cream. One subject had a mild vaginal burning sensation following application of Sildenafil Cream and placebo cream, which resolved itself and did not require any additional intervention or study withdrawal. Three subjects withdrew from the study for asymptomatic orthostatic tachycardia that occurred during the multiple serial blood draws for pharmacokinetics and one subject withdrew due to bacterial vaginosis. Among the 13 enrolled subjects, ten had adequate paired plasma samples from all three treatments to evaluate. Plasma PK of sildenafil following a single topical (applied externally to the pre-specified vulvar area and internally intravaginally) administration of Sildenafil Cream was characterized and findings were similar to those reported in a prior Phase 1 PK study conducted by our licensor SST.

In June 2023, we announced topline results from our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream in premenopausal women with FSAD, and in July and November 2023, we announced additional findings based on further analyses of data from the study. In 2024, several peer-reviewed journal articles were published on the study, including efficacy findings in *Obstetrics & Gynecology*, the official journal of the American College of Obstetricians and Gynecologists (ACOG), and safety findings in *The Journal of Sexual Medicine*, the official journal of the International Society for the Study of Women's Sexual Health (ISSWHS). In February 2024, we presented additional findings from the study at the Annual Meeting of ISSWHS. In addition, efficacy findings from the study were the featured topic of ACOG Green Room Gynecology Podcast in August 2024.

During the multi-center, double-blind, randomized, placebo-controlled study, subjects used Sildenafil Cream and placebo cream in their home setting over 12 weeks following a 4-week non-drug run-in period and a 4-week, single-blind placebo run-in period. A total of 252 subjects were enrolled in the 4-week single-blind placebo run-in period and a total of 200 subjects were randomized to the 12-week double-blind dosing period. A total of seven subjects were randomized but not treated in the double-blind dosing period. In the intent to treat (ITT) population, 99 subjects were randomized to the Sildenafil Cream group and 94 subjects were randomized to the placebo cream group. A total of 174 participants completed the study (Sildenafil Cream, n=90, placebo cream, n=84). The study did not meet its co-primary or secondary endpoints, which were measured based on the ITT population. Among the ITT population, which included women with only FSAD as well as those with FSAD and concomitant sexual dysfunction diagnoses or genital pain, though the Sildenafil Cream group demonstrated greater improvement in the Sexual Function Questionnaire (SFQ28) Arousal Sensation (AS) Domain scores, there were no statistically significant differences between Sildenafil Cream and placebo cream users in the co-primary and secondary efficacy endpoints. An exploratory post-hoc subset of the ITT population with an enrollment diagnosis of FSAD with or without concomitant decreased desire randomized to Sildenafil Cream reported significant increases in their SFQ28 AS Domain score (LS Mean [SE] 2.03 [0.62]) compared to placebo cream (LS Mean [SE] 0.08 [0.71]), p=0.04. This subset achieved a larger mean improvement in the SFQ28 Desire and Orgasm Domain scores. This subset population also had significantly reduced sexual distress and interpersonal difficulties with Sildenafil Cream use, as measured by Female Sexual Distress Scale-Desire, Arousal, Orgasm (FSDS-DAO) questions 3, 5, and 10 (all p values≤0.04). In summary, Sildenafil Cream improved outcomes among women with FSAD, most significantly in those who did not have concomitant orgasmic dysfunction. In particular, in an exploratory analysis of a subset of women with FSAD with or without concomitant decreased desire, Sildenafil Cream increased sexual arousal sensation, desire, and orgasm and reduced sexual distress.

During the 12-week double-blind dosing period, there were 78 TEAEs reported by 29 of the 99 Sildenafil Cream-assigned participants and 65 TEAEs reported by 28 of the 94 placebo cream-assigned participants (p=0.76). All TEAEs were mild or moderate in severity. The most common treatment-related TEAE among these participants was application site discomfort. There were no differences in the number of treatment-related TEAEs among Sildenafil Cream versus placebo cream users (p>0.99). Four Sildenafil Cream participants and three placebo cream participants discontinued the study due to TEAEs involving application site discomfort (p>0.99). There were 9 TEAEs reported by 7 of 91 sexual partners exposed to Sildenafil Cream versus 4 TEAEs reported by 4 of 84 sexual partners exposed to placebo cream (p=0.54). These data demonstrate that Sildenafil Cream was well tolerated by exposed users and their sexual partners.

Phase 3 Program

In January 2024, we announced the successful completion of an end-of-Phase 2 meeting with the FDA. We and the FDA aligned on key elements of the Phase 3 program to support an NDA filing, including confirming that FSAD is acceptable as an indication, the clinical trials can be conducted in a premenopausal-only FSAD population, and 12-weeks of blinded treatment to assess efficacy may be acceptable, provided that the trials are adequately powered for efficacy assessment. This is a shorter period of blinded treatment than the 24 weeks recommended in the FDA's 2016 draft guidance for industry on developing drugs for the treatment of low sexual interest, desire and/or arousal in women.

In December 2024, we announced plans for a Phase 3 study of Sildenafil Cream reflecting further FDA feedback for safety and efficacy evaluations to support the indication of treatment of FSAD in premenopausal women. Consistent with the Phase 2b RESPOND study, the planned Phase 3 study will include a 12-week, double-blind treatment period evaluating Sildenafil Cream compared to placebo cream in patients with FSAD with or without concomitant decreased desire. The currently planned Phase 3 study will have co-primary efficacy endpoints- one assessing arousal sensations and one assessing associated distress, which will be the same co-primary endpoints for arousal sensations and associated distress used in the Phase 2b RESPOND study. In addition, secondary efficacy endpoints to assess improvement in orgasm, desire, and distress and interpersonal difficulties will be included in the Phase 3 study, as they were in the Phase 2b RESPOND study.

We plan to submit the protocol and statistical analysis plan for an adequate and well-controlled Phase 3 clinical study, reflecting the FDA's recommendations, to the FDA in the second quarter of 2025, pending review of additional forthcoming recommendations from the FDA that impact our statistical analysis plan. We are targeting 2025 for commencement of the Phase 3 study pending the forthcoming FDA recommendations. We do not plan to conduct the Phase 3 study until after we secure additional capital.

A second confirmatory Phase 3 study will be required to support the NDA submission. We anticipate that each

Phase 3 study will be approximately $15.0 million in direct R&D costs (as defined below).

We are developing Sildenafil Cream with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC (which we refer to collectively as SST) under our license and collaboration agreement announced in February 2018. See “Strategic Agreements for Pipeline Development” below for discussion of the terms of this collaboration.

DARE-HRT1

DARE-HRT1 is a unique intravaginal ring, or IVR, designed to deliver bio-identical 17β-estradiol and bio-identical progesterone continuously over a 28-day period as part of a menopausal hormone therapy regimen. The IVR technology used in DARE-HRT1 was developed by Dr. Robert Langer from the Massachusetts Institute of Technology and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School. Unlike other vaginal ring technologies, ours is designed to release drugs via a solid ethylene vinyl acetate polymer matrix without the need for a membrane or reservoir to contain the active drug or control the release, allowing for sustained drug delivery over time periods ranging from weeks to months. Hormone therapy is considered the most effective treatment for vasomotor symptoms, or VMS, commonly referred to as hot flashes, and the genitourinary syndrome of menopause, or GSM, and it has been shown to prevent bone loss and fracture.

Following clinical development, we intend to leverage the large body of existing safety and efficacy data on estradiol and progesterone, the active ingredients in DARE-HRT1, to utilize the FDA's 505(b)(2) pathway to obtain marketing approval in the U.S. of DARE-HRT1 for the treatment of moderate-to-severe VMS due to menopause in women with intact uteri. Based on pre-IND communications with the FDA and the topline PK data from our Phase 1/2 clinical trial of DARE-HRT1, which is discussed below, we believe FDA approval of DARE-HRT1 for that indication is achievable via the FDA's 505(b)(2) pathway supported by a single, placebo-controlled Phase 3 clinical trial of DARE-HRT1, with safety evaluations out to 12 months, and a scientifically justified PK “bridge” (via a relative bioavailability trial) between DARE-HRT1 and the selected listed estradiol and progesterone drugs. We are conducting activities necessary to enable submission of an IND application to the FDA for a pivotal Phase 3 clinical study of DARE-HRT1. We do not plan to conduct the Phase 3 study until after we secure additional capital.

There are currently no FDA-approved IVRs that deliver bio-identical progesterone in combination with bio-identical estradiol. As such, DARE-HRT1 has the potential to be a first-in-category product that offers monthly convenience for women, and non-oral concurrent dosing of bio-identical progesterone in combination with bio-identical estradiol.

Clinical Data

In January 2023, data from our Phase 1 clinical trial of DARE-HRT1 conducted by our wholly owned subsidiary in Australia were published in *Menopause: The Journal of The North American Menopause Society,* or the *Menopause* journal, in an article entitled, “Evaluation of 28-day estradiol and progesterone vaginal rings in a phase 1 clinical pharmacokinetic study.” We previously announced positive topline results from the study in June 2021. The randomized, open-label, three-arm, parallel group trial evaluated the PK and safety of DARE-HRT1 in approximately 30 healthy, postmenopausal women with intact uteri, and was conducted by our wholly-owned Australian subsidiary at two specialty women's health sites in Australia. Women in the first arm received one IVR designed to release 17β-estradiol (E2) at a rate of 80 µg/d and progesterone (P4) at 4 mg/d, or the 80/4 IVR. Women in the second arm received one IVR designed to release E2 at a rate of 160 µg/d and P4 at 8 mg/d, or the 160/8 IVR. Women in the third arm received oral Estrofem® (1 mg E2) and oral Prometrium® (100 mg P4) both daily for 29 days. The primary objective of the study was to describe the PK parameters of the 80/4 IVR and the 160/8 IVR. Secondary endpoints of the study were to assess the safety and tolerability of the IVRs and compare the systemic exposure of E2, estrone, and P4 in the IVR groups with the oral group. Blood samples were taken predose then intensively over the first day (Day 1) and periodically thereafter over the remaining 27 days. After removal of the IVRs on the morning of Day 29, intensive samples were collected. Similar procedures were conducted with women enrolled in the oral group.

The journal article concluded that the 80/4 IVR and the 160/8 IVR gave similar steady-state concentrations of E2 as seen with drug products approved by the FDA for treatment of VMS and genitourinary symptoms of menopause, and that the E2 concentrations of the study support the potential of DARE-HRT1 as a new option for hormone therapy for treatment of VMS and vaginal symptoms associated with menopause. The IVRs were well tolerated, and no SAEs were reported.

DARE-HRT1 has also been evaluated in a Phase 1/2 clinical trial conducted by our wholly owned subsidiary in Australia. The randomized, open-label, two-arm, parallel group Phase 1/2 study of DARE-HRT1 was designed to

evaluate the PK of the same two versions of DARE-HRT1 as were evaluated in our earlier Phase 1 clinical study, the 80/4 IVR and the 160/8 IVR, in approximately 20 healthy, postmenopausal women with intact uteri. In the study, women were randomized (1:1) to either the 80/4 IVR or the 160/8 IVR and used DARE-HRT1 for three 28-day cycles, inserting a new IVR monthly. The study also collected safety, usability, acceptability and symptom-relief data, including VMS as well as the vaginal symptoms of menopause. Preliminary GSM treatment efficacy was estimated by measuring changes from baseline in vaginal pH, vaginal maturation index (VMI), and changes in the severity of GSM symptoms. Preliminary systemic VMS efficacy was measured by changes in responses to the Menopause-Specific Quality of Life (MENQOL) questionnaire. Acceptability was assessed by product experience surveys.

In 2023, data from the Phase 1/2 study of DARE-HRT1 were published in the *Menopause* journal in articles entitled, "A phase 1/2, open-label, parallel group study to evaluate the safety and pharmacokinetics of DARE-HRT1 (80 µg estradiol/4 mg progesterone and 160 µg estradiol/8 mg progesterone intravaginal rings) over 12 weeks in healthy postmenopausal women" (*Menopause* 30(8):p 817-823, August 2023) and "A phase 1/2, open-label, parallel group study to evaluate the preliminary efficacy and usability of DARE-HRT1 (80 µg estradiol/4 mg progesterone and 160 µg estradiol/8 mg progesterone intravaginal rings) over 12 weeks in healthy postmenopausal women" (*Menopause* 30(9):p 940-946, September 2023).

The first article (*Menopause* 30(8):p 817-823, August 2023) found that both versions of DARE-HRT1 evaluated in the Phase 1/2 study released E2 in systemic concentrations, which were in the low, normal premenopausal early folicular range and that systemic P4 concentrations were all in the normal post ovulatory range, which predicts endometrial protection. All TEAEs were mild or moderate and were distributed similarly among the 80/4 IVR and the 160/8 IVR users. The second article (*Menopause* 30(9):p 940-946, September 2023) found that (a) preliminary local GSM treatment efficacy was supported by significant decreases in vaginal pH and percentage (%) parabasal cells, and significant increases in the overall VMI and % superficial cells for both DARE-HRT1 groups (all P values <0.01) and (b) preliminary VMS efficacy was supported by significant decreases in all domains of the MENQOL questionnaire from baseline for both dosing groups (all P values <0.01). Both articles concluded that data from the Phase 1/2 study support further development of DARE-HRT1 for the treatment of menopausal symptoms.

We are developing DARE-HRT1 under our license agreement with Catalent JNP, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

DARE-VVA1

DARE-VVA1 is a proprietary investigational formulation of tamoxifen in a soft gelatin capsule for intravaginal administration. We are developing DARE-VVA1 as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of GSM (formerly called vulvar and vaginal atrophy or vulvovaginal atrophy (VVA)). Tamoxifen is a well-known and well-characterized selective estrogen receptor modulator, or SERM. Tamoxifen has unique properties that produce different effects (estrogen agonist or estrogen antagonist) in different types of tissues. In breast tissue, tamoxifen acts as an estrogen antagonist, meaning that it can inhibit estrogen's effect at the tissue level and hence why it may be effective in treating hormone-receptor positive (HR+) breast cancer. However, in other tissue, including vaginal tissue, tamoxifen has been reported to elicit an estrogen-like response. This has the potential to have a favorable effect on vaginal cytology and atrophy. GSM is an inflammation and thinning of the vaginal epithelium due to chronic hypo-estrogenism, which is the reduction in levels of circulating estrogen. Typical symptoms include vaginal dryness, itching and burning, and dyspareunia. GSM is a common condition in postmenopausal women and women with, or with a history of, HR+ breast cancer who received anti-cancer therapy. The prevalence of GSM in postmenopausal women is over 50% and survey data indicate only 56% of women experiencing menopausal vaginal changes discuss these symptoms with healthcare professionals, indicating that the syndrome is often underdiagnosed. Commonly used therapies for GSM are estrogen-based and are often contraindicated in HR+ breast cancer patients, or patients with a genetic predisposition or history of familial disease, because of the concern that estrogen use will promote recurrence or occurrence of disease. We believe there is a clear unmet medical need for an effective non-hormonal treatment for moderate-to-severe dyspareunia, a symptom of GSM .

In December 2023, we announced FDA clearance of our IND application for DARE-VVA1, which was supported by results from our Phase 1/2 clinical study of DARE-VVA1 (discussed below), and we are conducting activities in preparation for a Phase 2 randomized, double-blinded, placebo-controlled, dose-finding clinical study of DARE-VVA1 for moderate-to-severe dyspareunia. At the conclusion of our development program, if successful, we intend to leverage the existing safety and efficacy data for tamoxifen to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-VVA1 in the U.S.

Clinical Data

An exploratory study of vaginal administration of tamoxifen in four healthy postmenopausal women diagnosed with VVA published in *Clinical and Experimental Obstetrics & Gynecology* (2019, 46(2), 285-288) demonstrated that tamoxifen self-administered intravaginally for three months clinically benefited women with symptoms of VVA without significant systemic absorption of the study drug. In the open-label prospective cohort study with no placebo arm, participants were instructed to self-administer a vaginal suppository containing tamoxifen (20 mg) daily for one week and twice weekly for three months. Overall, the study drug was well tolerated. The primary efficacy endpoints evaluated normalization of vaginal pH and improvement of vaginal dryness. Vaginal pH and dryness scores using a visual analog scale were recorded at enrollment and subsequent assessments were recorded using self-assessment questionnaires over a three-month period. Both vaginal pH and vaginal dryness symptoms showed significant improvement after three months compared to baseline, with an approximately 30% improvement in vaginal pH scores and an approximately 63% improvement in vaginal dryness scores. The secondary endpoint was the measurement of tamoxifen concentrations after eight weeks of vaginal tamoxifen administration. When measured after eight weeks on the study treatment, serum tamoxifen levels were negligible, 5.8 ng/ml (median), with a range of 1.0 to 10.0 ng/ml. In comparison, after three months of once daily administration of oral dose of 20-mg tamoxifen, Nolvadex® (tamoxifen citrate) tablets, the average steady state plasma concentration of tamoxifen is 122 ng/ml (range of 71 to 183 ng/ml).

DARE-VVA1 has also been evaluated in a Phase 1/2 clinical study conducted by our wholly-owned subsidiary in Australia. The randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study enrolled 17 postmenopausal women with moderate-to-severe VVA and evaluated the safety, tolerability, plasma PK and PD of DARE-VVA1. The age of the 17 study participants ranged from 49 to 68 years, with an average age of 60.9 years. Participants were randomly allocated to one of five treatment groups (approximately four participants per group) that evaluated four dose levels of DARE-VVA1 (1 mg, 5 mg, 10 mg, and 20 mg tamoxifen) and a placebo. Following a screening visit, DARE-VVA1 was self-administered by study participants intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants had serial blood sampling for PK analysis and underwent safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants attended a safety follow-up visit. Fourteen participants completed the study. The primary endpoints of the study evaluated the safety and tolerability of DARE-VVA1 by vaginal administration and determined the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints evaluated preliminary efficacy and PD of DARE-VVA1 in terms of the most bothersome vaginal symptom and changes in vaginal cytology and pH.

In November 2022, we announced topline results from the Phase 1/2 study of DARE-VVA1. In 2023, data from the study were published in Climacteric, the official journal of the International Menopause Society, in an article entitled, “Pharmacokinetics, safety and preliminary pharmacodynamic evaluation of DARE-VVA1: a soft gelatin capsule containing tamoxifen for the treatment of vulvovaginal atrophy.” The article concluded that DARE-VVA1 resulted in minimal systemic exposure to tamoxifen. Adverse events were mild to moderate in severity and distributed similarly among the DARE-VVA1 and placebo groups. Of the 15 participants who reported at least one TEAE, nine reported a TEAE related to the reproductive system, with vulvovaginal discomfort (n=5 participant reports) and vulvovaginal pruritus (n=4 participants reports) being the most common organ system preferred term. The mean local erythema scores for all visits, for all dosing groups, were in the none\absent (0) to mild (1) range, with a few outliers in the moderate (2) grading, with no discernible pattern or correlation to group. All endometrial width measurements assessed with transvaginal ultrasound were normal at baseline and at 57 days of treatment, with the maximum measurement not exceeding 4.0 mm. Plasma tamoxifen concentrations were highest among women using DARE-VVA1 20 mg, but the maximum mean (standard deviation) plasma tamoxifen concentrations on day 1 and day 56 of the treatment period were less than 14% of those measured after one oral tamoxifen dose. The article also concluded that preliminary efficacy data support further development of DARE-VVA1. The article found that DARE-VVA1 users had significant decreases from pre-treatment baseline in vaginal pH and proportion of vaginal parabasal cells ($p = 0.04$ for both endpoints). Plasma tamoxifen concentrations were significantly and negatively correlated with vaginal pH (Spearman $R = -0.51$, $p<0.01$) and % vaginal parabasal cells (Spearman $R = -0.53$, $p<0.01$). Plasma tamoxifen concentrations were significantly and positively correlated with % vaginal superficial cells (Spearman $R = 0.45$, $p<0.01$), % vaginal intermediate cells (Spearman $R = 0.45$, $p <0.01$) and total vaginal maturation index (VMI) (Spearman $R = 0.62$, $p<0.01$). Women randomized to use DARE-VVA1 10 mg or DARE-VVA1 20 mg experienced the largest treatment impact. The severity of vaginal dryness and dyspareunia decreased significantly from baseline with DARE-VVA1 use ($p = 0.02$ for both endpoints).

We acquired the DARE-VVA1 program through our acquisition of Pear Tree Pharmaceuticals in 2018. See "Strategic Agreements for Pipeline Development" below for discussion of that merger agreement.

DARE-HPV

DARE-HPV (formerly referred to as R-131-2 and DARE-CIN) is an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert, which we plan to develop for the treatment of genital human papillomavirus (HPV) infection in women as well as treatment of cervical intraepithelial neoplasia, or CIN (also known as cervical dysplasia), and other HPV-related pathologies. CIN is a precancerous condition in women strongly linked to HPV infection, the most common sexually transmitted infection in the U.S. Disease severity is classified on a scale from one to three based on how much epithelial tissue in the cervix has abnormal cells. There is no FDA-approved treatment for HPV infection and no non-surgical pharmaceutical intervention to treat CIN2 or CIN3 (collectively referred to as CIN2+). Current surgical procedures to treat cervical dysplasia are invasive and can adversely impact future pregnancies. We believe a non-surgical pharmaceutical approach could provide women with an important alternative to surgical procedures to treat cervical dysplasia.

We are conducting activities necessary to enable submission of an IND application to the FDA for a Phase 2 clinical study of DARE-HPV as a treatment for genital persistent HPV infection with high risk strains. The IND enabling activities, IND submission, and the Phase 2 study are expected to be supported by non-dilutive funding under awards granted by the federal government in 2024. See ITEM 7. "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS–Recent Events–Non-Dilutive Funding Awards for DARE-HPV," below.

Clinical Data

An earlier non-optimized formulation of the same two active pharmaceutical ingredients in DARE-HPV was previously evaluated in 23 non-pregnant, healthy, premenopausal, HIV un-infected Kenyan women with CIN2 or CIN3 in an open-label, proof-of-concept clinical study with all women receiving a 4:1 (133 mg lopinavir and 33 mg ritonavir) oral tablet (Lopimune) which is FDA approved for the treatment of human immunodeficiency virus (HIV), but dosed vaginally twice daily for 14 days in this study. There were no SAEs. The most common TEAEs were headache (3/23, 13%) followed by vaginal irritation (2/23, 8.7%); nausea (2/23, 8.7%); feeling faint/dizziness (2/23, 8.7%), abnormal vaginal discharge (2/23 8.7%); and abdominal pains (1/23 4.3%). In total, 5/23 or 21.7% of study subjects experienced some form of minor complaint within the first month of taking Lopimune as described. The results demonstrated its potential as a self-applied therapy for HPV infection and related cervical lesions. The proof-of-concept study is published in the Public Library of Science (PLoS) One. DARE-HPV was also previously evaluated in 12 healthy, non-pregnant, premenopausal women without high-risk HPV or CIN, in a double-blind, placebo controlled, Phase 1 clinical study to assess PK and safety in New Zealand. Participants inserted one tablet vaginally daily for 21 days. Participants reported the amount of vaginal or vulvar irritation they experienced daily using a Likert scale ranging from 0 (none) to 1 (mild, does not require medical attention) to 2 (moderate, requires medical attention) to 3 (severe, requires medical attention and results in study medication being stopped). The mean daily vaginal irritation score was 1.47 ± 1.29 for active product users (n=8) versus 1.40 ± 0.9 for placebo product users (n=4).

We are developing DARE-HPV under our license agreement with Douglas Pharmaceuticals, Limited. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

DARE-PDM1

DARE-PDM1 is an investigational proprietary hydrogel formulation of diclofenac for vaginal administration designed to treat primary dysmenorrhea. DARE-PDM1 utilizes our proprietary hydrogel technology to vaginally deliver the active pharmaceutical ingredient, diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), in a novel way for the treatment of primary dysmenorrhea. Primary dysmenorrhea is defined as painful menstruation in girls and women with normal pelvic anatomy, typically described as cramping pain in the low back or lower abdomen before or during the menstrual period. Oral NSAIDs, such as diclofenac, are often recommended for temporary relief from the painful symptoms of primary dysmenorrhea. Because there are currently no FDA-approved vaginal diclofenac treatment options for primary dysmenorrhea, DARE-PDM1 has the potential to be a first-in-category product, delivering diclofenac in a convenient vaginal format that may extend the duration of pain relief and reduce the risks associated with the oral delivery of NSAIDs. According to the American College of Obstetricians and Gynecologists' Committee on Adolescent Health Care, dysmenorrhea is the most common menstrual symptom among adolescent girls and young women, and most adolescents experiencing dysmenorrhea have primary dysmenorrhea. Prevalence rates of dysmenorrhea vary but range from 50% to 90%.

Clinical Data

DARE-PDM1 has been evaluated in a Phase 1 clinical study, DARE-PDM1-001, conducted by our wholly-owned subsidiary in Australia. DARE-PDM1-001 was a multi-center, randomized, placebo-controlled, double-blind, three-arm parallel group study that enrolled approximately 42 healthy, premenopausal women with symptomatic primary dysmenorrhea. This study was designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac PK and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo (vaginal hydrogel, no active ingredient). The study also assessed, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period encompassed approximately three menstrual cycles.

In December 2023, we announced topline data from the DARE-PDM1-001 study. Participants received 1% diclofenac (n=14), 3% diclofenac (n=14) or placebo (n=14). All 42 participants completed the nine study visits. The topline data indicate that the study treatment was well-tolerated, and TEAE profiles were comparable between the DARE-PDM1 treatment groups and the placebo group. All adverse events were mild or moderate; most adverse events (85%) were mild. There were no early discontinuations due to an adverse event, and no SAEs were reported. The most common TEAEs were nausea, vomiting and abdominal discomfort, followed by vulvovaginal candidiasis and pelvic discomfort.

The vaginal fluid PK results exhibited dose proportionality for the 1% and 3% diclofenac strengths of the DARE-PDM1 study treatment. Additionally, the vaginal fluid PK results demonstrated that for approximately 75% (21/28) of the women in the DARE-PDM1 treatment groups the product was retained in the vaginal canal through 24 hours. The plasma PK results similarly exhibited dose proportionality for the 1% and 3% diclofenac strengths of the DARE-PDM1 study treatment. Plasma levels of diclofenac were at peak plasma concentrations within 3-4 hours for both diclofenac strengths of the DARE-PDM1 study treatment, and diclofenac was no longer detectable in the plasma by 48 hours post study treatment for the majority of subjects in the study. The plasma PK results for both DARE-PDM1 treatment groups indicate that vaginal dosing could result in systemic exposure which is approximately 1,000 times less than that seen from oral use of diclofenac.

The exploratory endpoint that evaluated the preliminary efficacy of DARE-PDM1 versus placebo in reducing dysmenorrhea-associated pain showed a promising signal, with a statistically significant decrease in pelvic/vaginal and lower back pain scores in the 1% diclofenac DARE-PDM1 treatment group compared to the placebo group, as well as a decrease in pain scores in the 3% diclofenac DARE-PDM1 treatment group. Additionally, while most participants used at least one non-pharmacologic pain relief method (e.g., heating pad) for dysmenorrhea-associated pain during the no-treatment, baseline, control cycle, the proportion of participants who used at least one non-pharmacologic pain relief method for dysmenorrhea-associated pain decreased significantly in the DARE-PDM1 treatment groups during the dosing period, but not in the placebo group. There was no difference in the exploratory assessment of frequency of use of rescue medications in the treatment phase between the three groups.

We believe the topline results of the Phase 1 study support continued clinical development of DARE-PDM1 as a treatment for primary dysmenorrhea. At the conclusion of the development program, if successful, we intend to leverage the existing safety and efficacy data for diclofenac to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-PDM1 in the U.S.

We are developing DARE-PDM1 under our agreements with TriLogic Pharma, LLC, MilanaPharm LLC and Hammock Pharmaceuticals, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of those agreements.

DARE-204 and DARE-214

DARE-204 and DARE-214 are formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively. These product candidates are being developed as a sub-cutaneous injectable, longer-acting, reversible method of contraception with a more predictable return to fertility. We plan to conduct Phase 1 clinical studies of DARE-204 and DARE-214 in Australia through our wholly-owned subsidiary in Australia. Additional manufacturing activities are necessary to commence the Phase 1 studies and these activities have not commenced. If we exercise our option and enter into an exclusive worldwide license agreement for DARE-204 and/or DARE-214, at the conclusion of these development programs, if successful, we intend to leverage the existing safety and efficacy data for etonogestrel to utilize the FDA's 505(b)(2) pathway to obtain marketing approval in the U.S.

We are developing DARE-204 and DARE-214 under our development and option agreement with Adare Pharmaceuticals USA, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

DARE-FRT1 and DARE-PTB1

DARE-FRT1 and DARE-PTB1 are IVRs designed to release bio-identical progesterone continuously for up to 14 days. DARE-FRT1 is being developed for luteal phase support as part of an in vitro fertilization, or IVF, treatment plan. DARE-PTB1 is being developed for the prevention of preterm birth. DARE-FRT1 and DARE-PTB1 use the same IVR technology platform as DARE-HRT1. We are conducting development activities to support IND submissions and Phase 1 clinical studies of these product candidates. We have a grant award from the NIH to support a Phase 1 study of DARE-PTB1, but do not plan to conduct the Phase 1 studies until after we secure additional capital. At the conclusion of these development programs, if successful, we intend to leverage the existing safety and efficacy data for progesterone to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-FRT1 and DARE-PTB1 in the U.S.

We are developing DARE-FRT1 and DARE-PTB1 under our license agreement with Catalent JNP, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

Casea S

Casea S is an investigational biodegradable contraceptive implant. Casea S is designed to control release of a well-characterized contraceptive, etonogestrel, for a set period of time (18-24 months) before dissolving. It is designed to provide women with a long-acting, minimally-invasive contraceptive method that will not require surgical removal by a healthcare provider, which would improve convenience and could eliminate one of the barriers to use associated with existing implanted contraceptives. Casea S is being tested in a single-center, two-part Phase 1 clinical study to evaluate the PK of etonogestrel, removability, safety, and tolerability of Casea S pellets inserted subdermally in healthy women of reproductive age (ClinicalTrials.gov ID: NCT05174884). The ongoing Phase 1 study is being conducted by FHI 360, a nonprofit organization, with support from the Foundation. There are no development costs to us at this time.

Casea S was recently acquired by Theramex. In February 2025, we entered into a co-development and licensing agreement with Theramex for the development of Casea S in the U.S. If we determine that the results from the Phase 1 study are positive and elect to proceed with development, we would be responsible for conducting a Phase 2 study in the U.S., In accordance with our agreement, the costs of such Phase 2 study would be shared by us and Theramex on terms to be agreed upon, taking into account the size of the opportunity for Casea S in our respective markets. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

503B Compounding

Sildenafil citrate is currently listed as a nominated bulk drug substance that may be used in compounding by 503B-registered outsourcing facilities, and we are taking action to make our proprietary Sildenafil Cream formulation available via prescription under Section 503B of the FDCA. Under Section 503B of the FDCA, outsourcing facilities, which must be registered with the FDA and are subject to current Good Manufacturing Practice, or cGMP, requirements and FDA inspections, may provide compounded drugs without an individual patient prescription. See "Government Regulation—U.S. Government Regulation—Regulation of Compounded Drugs" below for additional

information regarding compounding under Section 503B of the FDCA. We are targeting to make our proprietary Sildenafil Cream formulation available in the fourth quarter of 2025. For additional information, see ITEM 7. “MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS–Recent Events–Sildenafil Cream as a Compounded Drug,” below.

Our Pipeline: Pre-Clinical Stage Programs

Our pre-clinical stage programs include:

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- **DARE-PTB2**, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein.

DARE-LARC1, our potential user-controlled, long-acting reversible contraceptive, is designed to store and precisely deliver hundreds of therapeutic doses of the contraceptive levonorgestrel over a period of years and to be controlled by the user, without further intervention by a healthcare provider. DARE-LARC1’s woman-centered design seeks to offer the benefits of traditional long-acting reversible contraceptives with the added flexibility and convenience for the user to pause and resume release of levonorgestrel, depending on her desire for fertility or contraceptive protection. Under a grant agreement we entered into in June 2021, as amended, we may receive up to approximately $49.0 million, payable over approximately five years, to advance development of the technology through nonclinical proof of principle studies to enable an IND submission. As of the date of this report, we have received payments totaling approximately $31.8 million under the grant agreement. Additional payments are contingent upon the DARE-LARC1 program's achievement of development and reporting milestones specified in the grant agreement.

The DARE-LBT program has been supported by a private foundation grant of approximately $585,000 under a grant agreement that we entered into in November 2022. The grant funds supported activities related to development of a vaginal thermosetting gel formulation for the delivery of live biotherapeutics that can be reconstituted at the point of care. We believe DARE-LBT merits further development as a delivery vehicle with potential to enhance the availability of novel therapeutics for vaginal health in the United States and worldwide, including in countries with varying climatic conditions and/or where extended storage may be required.

Sales and Marketing

We do not have established marketing, sales or distribution infrastructure or capabilities. In order to commercialize any of our product candidates if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. Our approach is to develop an appropriate commercialization strategy for each of our product candidates based on the size of the market opportunity, the level of competition and the anticipated complexity of the launch. As we move our product candidates through development toward, and in some cases, through regulatory approval, we evaluate several options for each product candidate's commercialization strategy. These options include building our own sales force and other commercial infrastructure, entering into strategic marketing partnerships with third parties, including commercial sales organizations or other pharmaceutical or biotechnology companies, out-licensing the product to other pharmaceutical or biotechnology companies, and combinations of these strategies. Organon has global commercial rights to XACIATO under our exclusive license agreement, and we have an exclusive license agreement with Bayer to out-license U.S. commercialization of Ovaprene. Each of these collaborators has established marketing, sales and distribution capabilities in women's health. We expect to continue to evaluate each product opportunity and pursue the commercialization strategy that we believe will maximize the return on our assets in and outside of the U.S. for our stockholders. We have engaged third parties to assist in commercial planning and other commercial readiness activities for our product candidates and intend to continue to do so, as needed.

See “Strategic Agreements for Product Commercialization” below for a discussion of the terms of our out-license agreements.

Manufacturing and Supply

We do not own or operate, nor do we expect to own or operate, facilities for manufacturing, storage and distribution, or testing of our product candidates. We rely on third parties to supply and manufacture our product candidates and other materials necessary to conduct pre-clinical testing, clinical trials and other activities required for regulatory approval of our product candidates, and expect to continue to do so in the future. In addition, to the extent our commercialization strategy for any future approved product requires that we undertake commercial supply obligations, we intend to rely on contract manufacturers and suppliers for manufacture, storage, distribution and testing of our finished commercial products and their respective components, including the active pharmaceutical ingredients, or API. These arrangements require less upfront capital expenditure and allow us to maintain a smaller and more flexible infrastructure.

Under the terms of our license agreement with Organon, we were responsible for providing product supply of XACIATO on an interim basis until Organon assumed such responsibility. In March 2022, we entered into a long-term supply and manufacturing agreement with the contract manufacturing organization, or CMO, that provided clinical supplies of XACIATO for our pivotal Phase 3 DARE-BVFREE clinical study. Under the terms of our agreement, the CMO was responsible for obtaining supplies, at our expense, of all components necessary for the manufacture of XACIATO, including the API, clindamycin. In December 2023, Organon assumed our obligations under the agreement with the CMO and our product supply agreement with Organon was terminated.

Under our agreement with ADVA-Tec, ADVA-Tec is responsible for providing all clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, and except under limited circumstances, we may not obtain supplies of Ovaprene from any source other than ADVA-Tec or its CMO and licensor, Poly-Med, Inc. Other than our agreement with ADVA-Tec, we have no long-term arrangements for the production or supply of our product candidates or the materials required to produce them.

Under the terms of our license agreement with SST, SST was responsible for providing clinical supplies of Sildenafil Cream for Phase 2 clinical studies in the U.S., and we are responsible for providing supplies of Sildenafil Cream for Phase 3 clinical development and, if approved, for marketing and sale. Currently, we plan to obtain clinical supplies of Sildenafil Cream from the same CMO that manufactured Sildenafil Cream for the Phase 2b RESPOND clinical study.

We expect that our current arrangements will meet our foreseeable needs for clinical trial materials or, generally, that alternative supply sources will be readily available. However, we may experience manufacturing and supply delays and disruptions in the event we need to engage alternative supply sources, as well as in connection with our current CMOs scaling up production to meet our clinical supply requirements for later stage clinical studies. In addition, some key raw materials or components of our clinical-stage product candidates, including Ovaprene and Sildenafil Cream, have only a single source of supply and alternative supply sources may not be readily available. Global supply chain disruptions, including those related to recent and ongoing geopolitical events, may contribute to manufacturing and supply delays. See ITEM 1A. "RISK FACTORS – Risks Related to Product Research & Development and Regulatory Approval – Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products" below.

Strategic Agreements for Product Commercialization

Organon License Agreement

In March 2022, we entered into an agreement with Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property we control. In 2022, we received a $10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue. In 2023, Organon paid us $1.0 million in connection with entering into an amendment to our license agreement, which was also recorded as license fee revenue, and $1.8 million in connection with the first commercial sale of a licensed product in the United States, which was recorded as milestone revenue.

Under the terms of our license agreement, as amended, Organon agreed to pay tiered double-digit royalties based on net sales and potential future milestone payments of up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets. The royalty period for each licensed product will continue on a country-by-country basis from the first commercial sale of the licensed product in the country until the expiration of the later of (i) the date that no valid patent claim would be infringed in the absence of the license granted under the agreement by the sale of the licensed product in the country, (ii) 10 years after the end of the month in which the first commercial sale of the licensed product in the country occurred, and (iii) the expiration of regulatory market exclusivity for the licensed product in that country.

As described below, in April 2024, we sold to XOMA our rights to all royalty and potential milestone payments based on net sales of XACIATO under our license agreement with Organon, net of our obligations to certain third parties, until XOMA receives a specified return on its investment, after which we will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon.

Unless terminated earlier, our license agreement with Organon will expire on a product-by-product and country-by-country basis upon expiration of the applicable royalty period for each licensed product. In addition to customary termination rights for both parties, Organon may terminate the agreement in its entirety or on a country-by-country basis at any time in Organon's sole discretion on 120 days' advance written notice.

Our license agreement with Organon includes customary representations and warranties, covenants and indemnification obligations of each party. In addition, the agreement provides Organon exclusive worldwide rights of first negotiation for specified potential future products of ours.

Bayer License Agreement

In January 2020, we entered into a license agreement with Bayer regarding the further development and commercialization of Ovaprene in the U.S. We received a $1.0 million upfront non-refundable payment from Bayer and Bayer agreed to support us in development and regulatory activities by providing the equivalent of two experts to advise us in clinical, regulatory, preclinical, commercial, CMC and product supply matters. Bayer, in its sole discretion, has the right to make the license effective by paying us an additional $20.0 million, referred to as the Clinical Trial and Manufacturing Activities Fee. Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with us with regard to development.

Royalties and Milestone Payments Payable by Bayer. We will be entitled to receive (a) a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S. and escalating milestone payments based on annual net sales of Ovaprene during a calendar year, totaling up to $310.0 million if all such milestones, including the first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

As described below, in April 2024, we sold to XOMA a portion of our rights to the potential $20.0 million payment from Bayer described above and our rights to a portion of future net sales of Ovaprene under our agreement with Bayer.

Efforts. We will be responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and we have product supply obligations. After payment of the Clinical Trial and Manufacturing Activities Fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

Term. The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of (a) the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S.; or (b) 15

years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days' notice and the agreement will automatically terminate if we do not receive the Clinical Trial and Manufacturing Activities Fee if and when due.

Strategic Agreements for Pipeline Development

The following is a summary of certain rights and obligations under our strategic agreements and describes expenses incurred during 2024 and our future payment or potential future payment obligations thereunder.

Theramex Co-Development and License Agreement

In February 2025, we entered into a co-development and licensing agreement with Theramex for an investigational biodegradable contraceptive implant called Casea S recently acquired by Theramex. Under the agreement, we received a royalty-free, exclusive, fully paid up, sublicensable license to the U.S. patents Theramex recently acquired for Casea S. We paid a minimal fee to Theramex in connection with entering into the agreement. There are no development costs to us at this time. If we determine that the results from the ongoing Phase 1 clinical study are positive and elect to proceed with development, we would be responsible for conducting a Phase 2 study in the U.S. In accordance with our agreement, the costs of such Phase 2 study, and the costs of a future Phase 3 study in the U.S., would be shared by us and Theramex on terms to be agreed upon, taking into account the size of the opportunity for Casea S in our respective markets. If we do not elect to proceed with development after reviewing the results from the Phase 1 study, we may terminate the agreement upon notice to Theramex.

Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement

In August 2023, we entered into a license agreement with Douglas Pharmaceuticals Limited, or Douglas, under which we acquired the exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of CIN and other HPV-related pathologies, and an agreement with The University of Manchester, pursuant to which The University of Manchester consented to Douglas' sublicense to us of certain rights it previously granted to Douglas and agreed to grant us a direct license to such rights if its license agreement with Douglas is terminated. As a result of these agreements, we commenced our DARE-CIN program. Under our agreement with Douglas, we received an exclusive, royalty-bearing license to research, develop and commercialize the licensed intellectual property in the United States for the treatment or prevention of all indications for women in female reproductive health. We are entitled to sublicense the rights granted to us under the agreement.

Milestone Payments. We agreed to make potential future milestone payments to Douglas of (1) up to $5.25 million in the aggregate upon achieving certain development and regulatory milestones, which may be paid in shares of our common stock, in our sole discretion subject to specified limitations, and (2) up to $64.0 million in the aggregate upon achieving certain commercial sales milestones for each product covered by the licenses granted under the agreement.

Royalty Payments. Douglas is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on annual net sales of products and processes covered by the licenses granted under the agreement.

Efforts. We must use commercially reasonable efforts to develop and introduce to market at least one product or process.

Term. Unless earlier terminated, the agreement expires upon the expiration of the last-to-expire royalty term. In addition to customary termination rights for both parties, we may elect to terminate the agreement at any time, with or without cause, upon advance written notice to Douglas, and Douglas may terminate the agreement if we materially fail to fulfill diligence requirements with respect to product development.

Hennepin License Agreement

In August 2022, we entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which we acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. As a result of this license agreement, we commenced our DARE-GML program. Under the agreement, we received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. We are entitled to sublicense the rights granted to us under the agreement.

Milestone Payments. We agreed to make potential future development and sales milestone payments of (1) up to $6.25 million in the aggregate upon achieving certain development and regulatory milestones, and (2) up to $45.0 million in the aggregate upon achieving certain commercial sales milestones for each product covered by the licenses granted under the agreement, which may be paid, in our sole discretion, in cash or shares of our common stock.

Royalty Payments. Hennepin is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement.

Efforts. We must use commercially reasonable efforts to develop and introduce to market at least one product.

Term. Unless earlier terminated, the agreement expires in its entirety upon the last to expire royalty term. In addition to customary termination rights for both parties, we may elect to terminate the agreement at any time, with or without cause, on a country-by-country basis, and Hennepin may terminate the agreement if we do not undertake any development work with respect to the licensed intellectual property for five consecutive years from the date of the agreement.

Cooperative Research and Development Agreement with NICHD

In July 2021, we entered into a CRADA with the U.S. Department of Health and Human Services (HHS), as represented by NICHD, part of the NIH, for the conduct of a pivotal Phase 3 clinical study of Ovaprene. Pursuant to the terms of the CRADA, we are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million to NICHD to be applied toward the costs of conducting the Phase 3 study, all of which had been paid as of September 30, 2024. NICHD is responsible for the other costs related to the conduct of the Phase 3 study and for managing the payment of expenses to other parties involved with the study. However, for recent developments relating to NICHD's performance under the CRADA, see "Our Pipeline: Clinical Stage Programs–Ovaprene–Pivotal Phase 3 Clinical Study" above. Either we or NICHD may terminate the CRADA for any reason upon 30 days' prior written notice to the other party. If the CRADA is terminated before completion of the Phase 3 study, NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study. If we terminate the CRADA before the completion of any active study protocol, we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the study. NICHD may retain and use payments we make under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination, and any unused funds will be returned to us. Under the CRADA, each party granted the other party rights to use their respective background inventions solely to the extent necessary to conduct the activities described in the research plan in the CRADA. Subject to the U.S. government's nonexclusive, nontransferable, irrevocable, paid-up right to practice any CRADA invention for research or other government purposes, each party will own inventions, data and materials produced by its employees, and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed. The CRADA also contains customary representations, warranties, and indemnification and confidentiality obligations. The CRADA expires five years from its effective date.

MBI Acquisition

In November 2019, we acquired Dare MB Inc. (formerly, Microchips Biotech, Inc.), or MBI, to secure the rights to develop a long-acting reversible contraception method that a woman can turn on or off herself, according to her own needs. This candidate is now known as DARE-LARC1.

Under the terms of the merger agreement, the Company agreed to pay former MBI stockholders: (a) up to $46.5 million contingent upon the achievement of specified funding, product development and regulatory milestones; (b) up to $55.0 million contingent upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property the Company acquired in the merger; and (c) tiered royalty payments ranging from low single-digit to low double-digit percentages based on annual net sales of such products sold by the Company (but not by sublicensee) and a percentage of sublicense revenue related to such products.

In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events, $1.0 million of which was recorded as contingent consideration on our consolidated balance sheets upon the completion of the MBI acquisition and $250,000 of which was expensed in 2021. In July 2021, our board of directors elected to make these milestone payments in shares of our common stock, to the extent permissible under the terms of the merger agreement with MBI, and, in September 2021, we issued approximately 58,334 shares of our common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders' representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

TriLogic and MilanaPharm License Agreement / Hammock Assignment Agreement

In December 2018, we entered into (a) an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and (b) a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, we acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In XACIATO, this proprietary technology is formulated with clindamycin for the treatment of bacterial vaginosis. In December 2019, we entered into amendments to each of the Assignment Agreement and License Amendment. In September 2021, we entered into a second amendment to the License Agreement. In March 2022, in connection with entering into our exclusive license agreement with Organon, we entered into a consent, waiver and stand-by license agreement with TriLogic, MilanaPharm and Organon, which further amended the License Agreement.

License Amendment, as amended:

Milestone Payments. We paid MilanaPharm $500,000 in connection with the first commercial sale in the United States of XACIATO in the fourth quarter of 2023. We may pay up to $250,000 upon the first commercial sale in the United States of successive licensed products for each vaginal or urological use. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products, we must pay $1.0 million to MilanaPharm.

Foreign Sublicense Income. MilanaPharm is eligible to receive a low double-digit percentage of all income received by us or our affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions.

Royalty Payments. During the royalty term, MilanaPharm is eligible to receive high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes. The royalty term, which is determined on a country-by-country basis and licensed product-by-product basis (or process-by-process basis), begins with the first commercial sale of a licensed product or process in a country and terminates on the latest of (1) the expiration date of the last valid claim of the licensed patent rights that cover the method of use of such product or process in such country, or (2) 10 years following the first commercial sale of such product or process in such country. Royalty payments are subject to reduction in certain circumstances, including as a result of generic competition, patent prosecution expenses incurred by us, or payments to third parties for rights or know-how required for us to exercise the licenses granted to it under the MilanaPharm License Agreement or that are strategically important or could add value to a licensed product or process in a manner expected to materially generate or increase sales.

Efforts. We must use commercially reasonable efforts and resources to (1) develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany, Italy or Spain, and (2) continue to commercialize that product or process following the first commercial sale of a licensed product or process in the applicable jurisdiction.

Term. Unless earlier terminated, the license term continues until (1) on a licensed product-by-product (or process-by-process basis) and country-by-country basis, the date of expiration of the royalty term with respect to such licensed product in such country, and (2) the expiration of all applicable royalty terms under the MilanaPharm License Agreement with respect to all licensed products and processes in all countries. Upon expiration of the term with respect to any licensed product or process in a country (but not upon earlier termination of the MilanaPharm License Agreement), the licenses granted to us under the MilanaPharm License Agreement will convert automatically to an exclusive, fully paid-up, royalty-free, perpetual, non-terminable and irrevocable right and license under the licensed intellectual property.

In addition to customary termination rights for all parties, MilanaPharm may terminate the license granted to us solely with respect to a licensed product or process in a country if, after having launched such product or process in such country, (1) we or our affiliates or sublicensees discontinue the sale of such product or process in such country and MilanaPharm notifies us of such termination within 60 days of having first been notified by us of such discontinuation, or (2) we or our affiliates or sublicensees (A) discontinue all commercially reasonable marketing efforts to sell, and discontinue all sales of, such product or process in such country for nine months or more, (B) fail to resume such commercially reasonable marketing efforts within 120 days of having been notified of such failure by MilanaPharm, (C) fail to reasonably demonstrate a strategic justification for the discontinuation and failure to resume to MilanaPharm, and (D) MilanaPharm gives 90 days' notice to us.

Assignment Agreement, as amended

Assignment; Technology Transfer. Hammock assigned and transferred to us all of its right, title and interest in and to the MilanaPharm License Agreement and agreed to cooperate to transfer to us all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan to be agreed upon by the parties, with a goal for us to independently practice the licensed intellectual property as soon as commercially practical in order to develop and commercialize the licensed products and processes.

Milestone Payments. Hammock is eligible to receive up to $250,000 in the aggregate upon achievement of a regulatory development milestone related to a non-bacterial vaginosis product.

Term. The Assignment Agreement will terminate upon the later of (1) completion of the parties' technology transfer plan, and (2) payment to Hammock of the last of the milestone payments.

Pear Tree Acquisition and License Agreements

In May 2018, we completed our acquisition of Pear Tree Pharmaceuticals, Inc., or Pear Tree. We acquired Pear Tree to secure exclusive, sublicensable, worldwide rights under certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration. This acquisition led to our DARE-VVA1 program. Under the merger agreement, former stockholders of Pear Tree are eligible to receive tiered royalties based on net sales of licensed products by us or our affiliates, subject to customary reductions and offsets and to offset by royalty and sublicense revenue share payments payable to Pear Tree's licensors as further described below, and a percentage of sublicense revenue. Former stockholders of Pear Tree and Pear Tree's licensors are also eligible to receive payments based on achievement of specified clinical development, regulatory and commercial milestones by licensed products as further described below.

Milestone Payments. Former stockholders of Pear Tree are eligible to receive up to $15.5 million in the aggregate in payments based on the achievement of clinical development and regulatory milestones by licensed products and up to $47.0 million in the aggregate in payments based on the achievement of commercial milestones by licensed products. These payments shall only be due once upon the first occurrence any of the specified milestone events. In addition, licensors of Pear Tree are eligible to receive up to approximately $3.2 million in the aggregate in payments based on the achievement of clinical development, regulatory and commercial milestones by each licensed product. These milestone payments may be made, in our sole discretion, in cash or in shares of our common stock in accordance with the terms of the merger agreement and the license agreements.

Royalty Payments; Sublicense Revenue Share. Former stockholders of Pear Tree are eligible to receive tiered royalties based on single-digit to low double-digit percentages of annual net sales of licensed products by us or our affiliates, subject to customary reductions and offsets, and a portion of royalties we receive from sublicensees. These payments may be made, in our sole discretion, in cash or in shares of our common stock in accordance with the terms of the merger agreement. Pear Tree's licensors are eligible to receive semi-annual royalties based on a single-digit percentage of net sales of licensed products by us or our affiliates, subject to customary reductions and offsets, or a portion of any royalties received by us or our affiliates from sublicensees, and a low double-digit percentage of all sublicensing fees or other lump sum payments or compensation we receive from sublicensees, subject to customary exclusions. Portions of certain milestone payments made to Pear Tree's licensors may be creditable against royalty payments due to Pear Tree's licensors.

License Agreements Revenue Share Offset. Under the merger agreement, in addition to customary royalty reductions and offsets, royalty payments and payments based on income received from sublicensees of licensed products made by us to Pear Tree's licensors are creditable against all royalty and sublicense revenue share payments payable to former stockholders of Pear Tree.

Catalent JNP License Agreement

In April 2018, we entered into an exclusive license agreement with Catalent JNP, Inc. (formerly known as Juniper Pharmaceuticals, Inc., and which we refer to as Catalent in this report), under which Catalent granted us (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, to make, have made, use, have used, sell, have sold, import and have imported products and processes; and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Catalent to make, have made, use, have used, sell, have sold, import and have imported products and processes. As a result of this license agreement, we commenced our DARE-HRT1, DARE-FRT1 and DARE-PTB1 programs. We are entitled to sublicense the rights granted to us under this agreement.

Annual Maintenance Fee. We pay an annual license maintenance fee of $100,000 to Catalent on each anniversary of the date of the agreement, which will be creditable against royalties and other payments due to Catalent in the same calendar year (including milestone payments and sublicense income), but may not be carried forward to any other year.

Milestone Payments. Catalent is eligible to receive (1) up to $12.5 million in the aggregate in payments based on the achievement of specified clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate in payments based on the achievement of specified commercial sales milestones for each product or process covered by the licenses granted under the agreement.

Royalty Payments. During the royalty term, Catalent is eligible to receive mid single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, we will pay Catalent a low double-digit percentage of all sublicense income we receive for the sublicense of rights under the agreement to a third party. The royalty term, which is determined on a country-by-country basis and product-by-product basis (or process-by-process basis), begins with the first commercial sale of a product or process in a country and terminates on the latest of (1) the expiration date of the last valid claim within the licensed patent rights with respect to such product or process in such country, (2) 10 years following the first commercial sale of such product or process in such country, and (3) when one or more generic products for such product or process are commercially available in such country, except that if there is no such generic product by the 10th year following the first commercial sale in such country, then the royalty term will terminate on the 10-year anniversary of the first commercial sale in such country.

Efforts. We must use commercially reasonable efforts to develop and make at least one product or process available to the public, which efforts include achieving specific diligence requirements by specific dates specified in the agreement.

Term. Unless earlier terminated, the term of the agreement will continue on a country-by-country basis until the later of (1) the expiration date of the last valid claim within such country, or (2) 10 years from the date of first commercial sale of a product or process in such country. Upon expiration (but not early termination) of the agreement, the licenses granted thereunder will convert automatically to fully-paid irrevocable licenses. Catalent may terminate the agreement (1) upon 30 days' notice for our uncured breach of any payment obligation under the agreement, (2) if we fail to maintain required insurance, (3) immediately upon our insolvency or the making of an assignment for the benefit of our creditors or if a bankruptcy petition is filed for or against us, which petition is not dismissed within 90 days, or (4) upon 60 days' notice for any uncured material breach by us of any of our other obligations under the agreement. We may terminate the agreement on a country-by-country basis for any reason by giving 180 days' notice (or 90 days' notice if such termination occurs prior to receipt of marketing approval in the United States). If Catalent terminates the agreement for the reason described in clause (4) above or if we terminate the agreement, Catalent will have full access including the right to use and reference all product data generated during the term of the agreement that is owned by us.

Adare Development and Option Agreement

In March 2018, we entered into an exclusive development and option agreement with Adare Pharmaceuticals USA, Inc. (formerly known as Orbis Biosciences, Inc., and which we refer to as Adare), for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which we refer to as DARE-204 and DARE-214, respectively). The agreement, as amended, provides us with an option to negotiate an exclusive, worldwide, royalty-bearing license, with rights to sublicense, for the programs if we fund the conduct of specified development work. We have no obligation to exercise our option.

SST License and Collaboration Agreement

In February 2018, we entered into a license and collaboration agreement with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC, referred to collectively as SST, under which we received an exclusive, royalty-bearing, sublicensable license to develop and commercialize, in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of female sexual arousal disorder, or the Field of Use, SST's topical formulation of Sildenafil Cream as it existed as of the effective date of this agreement, or any other topically applied pharmaceutical product containing sildenafil or a salt thereof as a pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen, or the Licensed Products.

Invention Ownership. We retain rights to inventions made by our employees, SST retains rights to inventions made by its employees, and each party owns a 50% undivided interest in all joint inventions.

Joint Development Committee. The parties will collaborate through a joint development committee that will determine the strategic objectives for, and generally oversee, the development efforts of both parties under the agreement.

Development. We must use commercially reasonable efforts to develop the Licensed Products in the Field of Use in accordance with a development plan in the agreement, and to commercialize the Licensed Products in the Field of Use. We are responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it must perform under the agreement.

Royalty Payments. SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

Milestone Payments. SST will be eligible to receive payments (1) ranging from $0.5 million to $18.0 million in the aggregate upon achieving certain clinical and regulatory milestones in the U.S. and worldwide, and (2) between $10.0 million to $100.0 million in the aggregate upon achieving certain commercial sales milestones. If we enter into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST.

License Term. Our license continues on a country-by-country basis until the later of 10 years from the date of the first commercial sale of such Licensed Product or the expiration of the last valid claim of patent rights covering the Licensed Product in the Field of Use. Upon expiration (but not termination) of the agreement in a particular country, we will have a fully paid-up license under the licensed intellectual property to develop and commercialize the applicable Licensed Products in the applicable country on a non-exclusive basis.

Termination. In addition to customary termination rights for both parties: (1) prior to receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA approval, we may terminate the agreement without cause upon 90 days prior written notice; (2) following receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA approval, we may terminate the agreement without cause upon 180 days prior written notice; and (3) SST may terminate the agreement with respect to the applicable Licensed Product(s) in the applicable country(ies) upon 30 days' notice if we fail to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan and do not cure such failure within 60 days of receipt of SST's notice thereof.

ADVA-Tec License Agreement

In March 2017, we entered into a license agreement with ADVA-Tec, Inc., under which we were granted an exclusive license to develop and commercialize Ovaprene for human contraceptive use worldwide. We must use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, including $2.5 million per year to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first. ADVA-Tec will conduct certain research and development work as necessary to allow us to seek a PMA from the FDA. ADVA-Tec is responsible for providing us with clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, on commercially reasonable terms, and, except under limited circumstances, we may not obtain supplies of Ovaprene from another source.

Under the license agreement, in addition to an exclusive, sublicensable license to ADVA-Tec's and its affiliates' intellectual property rights for all uses of Ovaprene as a human contraceptive device, we have a right of first refusal to license these patents and patent applications for additional indications.

Milestone Payments. We may pay to ADVA-Tec: (1) up to $13.0 million in the aggregate based on the achievement of specified development and regulatory milestones and (2) up to $20 million in the aggregate based on the achievement of certain worldwide net sales milestones. The future development and regulatory milestones include: successful completion of a Phase 3/pivotal clinical trial; the FDA's acceptance of a PMA filing for Ovaprene; the FDA's approval of the PMA for Ovaprene; CE Marking of Ovaprene in at least three designated European countries; obtaining regulatory approval in at least three designated European countries; and obtaining regulatory approval in Japan.

Royalty Payments. ADVA-Tec is eligible to receive royalties based on aggregate annual net sales of Ovaprene in specified regions at a royalty rate that will vary between 1% and 10% and will increase based on various net sales thresholds, subject to customary reductions and offsets.

Sublicense Revenue Payments. If we sublicense our rights under the license agreement, in lieu of royalty payments to ADVA-Tec, ADVA-Tec is eligible to receive a double-digit percentage of sublicense revenue received by us during the royalty term; provided, however, that for sublicense revenue we receive prior to the first commercial sale of a licensed product that represents an upfront payment or license fee due on or around the effective date of the sublicense, ADVA-Tec is eligible to receive a single-digit percentage of that sublicense revenue.

Term. Unless earlier terminated, the license we received under the agreement continues on a country-by-country basis until the later of the life of the licensed patents or our last commercial sale of Ovaprene. In addition to customary termination rights for both parties: (A) we may terminate the agreement with or without cause in whole or on a country-by-country basis upon 60 days prior written notice; and (B) ADVA-Tec may terminate the agreement if we develop or commercialize any non-hormonal ring-based vaginal contraceptive device competitive to Ovaprene or if we fail to: (1) in certain limited circumstances, commercialize Ovaprene in certain designated countries within three years of the first commercial sale of Ovaprene; (2) satisfy the annual spending obligation described above, (3) use commercially reasonable efforts to complete all necessary pre-clinical and clinical studies required to support and submit a PMA, or (4) conduct clinical trials as set forth in the development plan to which we and ADVA-Tec agree, and as may be modified by a joint research committee, unless such failure is caused by events outside of our reasonable control.

Royalty Monetization Transactions

Traditional and Synthetic Royalty Purchase Agreements with XOMA

On April 29, 2024, we entered into a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (which, together, we refer to as the Royalty Purchase Agreements), and XOMA paid $22.0 million to us. In addition, if XOMA receives total payments under the Royalty Purchase Agreements (as described below) equal to an amount that exceeds $88.0 million (which we refer to as the Revenue Sharing Threshold), XOMA will pay $11.0 million to us for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements (such $11.0 million payments to us we refer to as the Contingent Purchase Price Payments).

Under the Royalty Purchase Agreements, we sold, assigned, transferred and conveyed our right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments we would otherwise have the right to receive from and after April 1, 2024 under our exclusive license agreement with Organon, based on net sales of XACIATO, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of us under our exclusive license agreement with third-party licensors TriLogic and MilanaPharm, and (ii) all payments due and payable and actually paid by or on behalf of us under our royalty interest financing agreement with United in Endeavour, LLC, or UiE, (such net amount we refer to as the Purchased Receivables);

(b) 25% of the potential future $20.0 million payment that we would otherwise have the right to receive under our license agreement with Bayer relating to Ovaprene, if Bayer, in its sole discretion, elects to make the license granted thereunder effective following completion of the pivotal clinical trial of Ovaprene; and

(c) a synthetic royalty of 4.0% of our, our affiliates' and our sublicensees' future net sales of Ovaprene, and 2.0% of our, our affiliates' and our sublicensees' future net sales of Sildenafil Cream; *provided, however*, that, if XOMA receives total payments under the Royalty Purchase Agreements, net of any Contingent

Purchase Price Payments made to us, equal to an amount that exceeds $110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (such amounts described in the foregoing clauses (b) and (c) we collectively refer to as the Revenue Participation Right).

Pursuant to the traditional royalty purchase agreement, XOMA, at its sole cost and discretion, may repay in full and retire all of our payment obligations to UiE under our royalty interest financing agreement with UiE. If XOMA does so, no further amounts in respect of that agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the traditional royalty purchase agreement. As of April 29, 2024, we cannot elect to receive any additional funding from UiE under our royalty interest financing agreement with UiE without XOMA's prior written consent.

In connection with the synthetic royalty purchase agreement, we granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream.

The Royalty Purchase Agreements contain certain representations and warranties regarding our rights and obligations with respect to our license agreement with Organon, our license agreement with Bayer and our in-license agreements relating to XACIATO, Ovaprene and Sildenafil Cream, as well as customary representations and warranties for a transaction of this nature. The Royalty Purchase Agreements also contain customary covenants for a transaction of this nature, including covenants that limit or restrict our ability to incur indebtedness or liens related to the Purchased Receivables, the Revenue Participation Right, and certain product assets related to Ovaprene and Sildenafil Cream (except pursuant to a suitable intercreditor agreement). The Royalty Purchase Agreements do not restrict our ability to out-license any of our products or product candidates.

Royalty Interest Financing Agreement

In December 2023, we entered into a royalty interest financing agreement with United in Endeavour, LLC, or UiE, pursuant to which we sold to UiE an interest in the royalty and milestone payments we receive from Organon in respect of net sales of XACIATO. On the effective date of the agreement, we received a payment of $5.0 million, or the Initial Investment, from UiE. Until December 31, 2026, we may, at our sole discretion, elect to receive three additional payments of up to an aggregate of $7.0 million. We refer to each such payment as a Supplemental Discretionary Investment Amount, and collectively, as the Total Supplemental Discretionary Investment Amount.

We will make payments to UiE under the agreement until such time when UiE has received aggregate payments equaling a 12% internal rate of return, or the IRR, on the Initial Investment and the Total Supplemental Discretionary Investment Amount, if any (referred to as the Hard Cap). Until such time as the IRR has been achieved, we agreed to make payments to UiE equal to (i) from the date of the agreement through December 31, 2025, 50% of the amount of royalty payments remaining after all amounts that are due and payable and actually paid by us to any licensor or sublicensee on the royalty payments generated and received by us on net sales of XACIATO by Organon have been deducted (such payments referred to as the Net Royalty Payments), (ii) from January 1, 2026 through December 31, 2029, 75% of the Net Royalty Payments, and (iii) from the date of the agreement through December 31, 2029, 10% of the amount of milestone payments remaining after all amounts that are due and payable and actually paid by us to any licensor or sublicensee on the milestone payments generated and received by us on net sales of XACIATO by Organon have been deducted. After December 31, 2029, we will be required to make certain additional payments to UiE to the extent UiE has not received payments equaling the Hard Cap by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if UiE has not received payments equaling the Hard Cap by December 31, 2035 and we have other sources of assets or income besides XACIATO sufficient to complete such payments, we have agreed to pay UiE quarterly payments evenly divided over a two-year term, such that UiE will have obtained the IRR, taking into account all other payments received by UiE from us under the agreement. UiE's right to receive payments will terminate when UiE has received the Hard Cap. We have the right, but not the obligation, at any time, to repurchase all of the interest from UiE at a repurchase price equal to the Hard Cap, calculated as of the date of we exercise such call option.

The agreement contains representations and warranties, covenants, indemnification obligations, and other provisions customary for transactions of this nature and will terminate on the date that is the earlier of (i) the date upon which the payment of the purchased interest in respect of XACIATO is made in full to UiE, and (ii) the payment to UiE of an aggregate amount equal to the Hard Cap.

In connection with the agreement, we issued to UiE a warrant to purchase up to 422,804 shares of our common stock. In addition, for every $1.0 million of Supplemental Discretionary Investment Amount, we agreed to issue an additional warrant to purchase up to 84,561 shares of our common stock, for an aggregate of additional warrants to purchase up to 591,927 shares of our common stock.

The warrants are exercisable, in full or in part, at any time on or prior to the fifth anniversary of the date of issuance of the particular warrant at an exercise price of $0.410 per share, subject to customary anti-dilution adjustments. The warrants may be exercised for cash, or if at the time of exercise there is no effective registration statement registering for resale the shares underlying the warrants, then in lieu of paying the exercise price in cash, the holder may elect to exercise the warrant on a cashless basis.

Intellectual Property

We actively seek to protect the proprietary technology that we consider important to our business in the United States and other jurisdictions internationally. We also rely upon trade secrets and contracts to protect our proprietary information.

Patents

The medical device and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any claim relating to infringement of third party patents that is successfully asserted against us or our licensors may require us to pay substantial damages or may limit our or our licensors' ability to rely on such patent protection. Any third party claim successfully alleging the invalidity or unenforceability of the patents may also limit our or our licensors' ability to rely on such patent protection. Even if we, or our licensors were to prevail in any such action, any litigation could be costly and time-consuming and would divert the attention of management and key personnel from our business operations. Also, if our product candidates or any future products are found to infringe the patents of others, our development, manufacture, and sale of these potential products could be severely restricted or prohibited. In addition, there can be no assurance that any patent applications filed by us or our licensors will result in the grant of a patent either in the United States or elsewhere, or that any patents granted will be valid and enforceable, or that any patents will provide a competitive advantage or afford protection against competitors with similar technologies. Because of the importance of the patents underlying our product candidates, our business and our prospects may be harmed if we fail to maintain existing or obtain new patent rights or if we and our licensors fail to protect key intellectual property rights.

Under the terms of the Assignment Agreement with Hammock Pharmaceuticals, Inc. and the License Amendment with TriLogic Pharma, LLC and MilanaPharm, LLC, regarding the thermosetting hydrogel platform which includes XACIATO, we are the exclusive licensee of three issued U.S. patents, two of which are set to expire in December 2028 and one of which is set to expire in September 2036, subject to any extensions or disclaimers, and three foreign patents, including one European Patent Office, or EPO, patent validated in four countries, that expire in December 2028, subject to any extensions or disclaimers, as well as two foreign patents, including one EPO patent validated in 22 countries, that expire in July 2036, subject to any extensions or disclaimers. One of the three issued U.S. patents is listed in the FDA's compendium of “Approved Drug Products with Therapeutic Equivalence Evaluation," known as the Orange Book, under the Patent Exclusivity Information for XACIATO. In addition, we have rights to three pending foreign patent applications and one pending U.S. patent application. If issued, the patent term for any patents issuing from these pending applications would be expected to expire in 2036, subject to any extensions or disclaimers. We own a pending U.S. application and 16 pending foreign applications regarding XACIATO, and a pending U.S. and five pending foreign applications directed to the thermosetting hydrogel platform. The patent term for any patents issuing from these pending applications would be expected to expire in 2042, subject to any extensions or disclaimers. Organon has licensed XACIATO-specific patents and applications from us.

Under the terms of the ADVA-Tec license agreement, regarding Ovaprene, we are the exclusive licensee of five granted U.S. patents, one pending U.S. patent application, seven granted foreign patents, including two EPO patents validated in a total of 36 countries, and two pending foreign patent applications. Two of the U.S. patents have terms until August 2028, which includes days added to the term by patent term adjustment, and a third patent has a term that expires in July 2027, including patent term adjustment, each of such terms being subject to any future extensions or disclaimers. The other U.S. and foreign patents are expected to expire in 2025 or 2026. The patent terms for any patents issuing from the pending applications would be expected to expire in 2035, subject to any extensions or disclaimers.

Under the terms of the SST license agreement, regarding Sildenafil Cream, we are the exclusive licensee in the Field of Use of 27 issued patents worldwide (11 U.S. patents and 16 foreign patents, including three EPO patents validated in a total of 20 countries). Additionally, there is one patent application pending in the US, one in Europe, and two in other international markets. The issued U.S. patents have a patent term that expires in June 2029, including any patent term adjustment, and may be eligible for regulatory exclusivity under the Hatch-Waxman Act, while several foreign patents have a term that is set to expire in late 2031, each of such terms being subject to any future

extensions or disclaimers. Additionally, relative to the sildenafil program, we are the sole owner of a pending PCT application with an expected term, if granted, until 2044, subject to any extensions or disclaimers.

Under the terms of the Catalent license agreement, regarding our intravaginal ring platform which includes DARE-HRT1, we are the exclusive licensee of two issued U.S. patents with patent terms set to expire in February 2025 and September 2027, including patent term adjustment. Additionally, relative to the DARE-HRT1 program, we are the sole owner of one pending PCT application with an expected term, if granted, until 2044, subject to any extensions or disclaimers.

When we acquired Pear Tree Pharmaceuticals, Inc. in 2018, regarding DARE-VVA1, we obtained the rights to three U.S. patents and one Japanese patent. The patent terms for the U.S. patents are expected to expire in June 2027, June 2028, and May 2035 including any patent term adjustment, extensions or disclaimers. The Japanese patent has a term that is set to expire in June 2027. Additionally, relative to the DARE-VVA1 program, we are the sole owner of one pending PCT application with an expected term, if granted, until 2044, subject to any extensions or disclaimers.

When we acquired MBI in 2019, we obtained the rights to over 100 patents and applications. The key technology underlying the platform currently is supported by 14 U.S. patents and 49 foreign patents, including six EPO patents validated in various European countries, and 12 pending patent applications. We believe that the four most recently filed patent families are directly applicable to our DARE-LARC1 program. Those patent families have patent terms that are set to expire 2032, 2033, 2034, 2040, and 2045 respectively, subject to any extensions or disclaimers. Those patent families include patents granted in the U.S., E.U. and other key international markets.

Under the terms of the Hennepin license agreement, we are the exclusive licensee of five issued U.S. patents and four foreign patents, as well as three pending U.S. applications and twelve pending foreign applications. The U.S. patents are set to expire in 2025, 2026, 2028, 2033 and 2034 including any patent term adjustment, extensions or disclaimers, and the foreign patents have patent terms until 2025 or 2033. The U.S. and foreign applications, if granted, are expected to have patent terms that expire in 2033, 2037, 2038, and 2042, subject to any extensions or disclaimers.

Under the terms of the Douglas license agreement, we are the exclusive licensee of four granted U.S. patents and four pending U.S. patent applications. The granted patents are expected to expire in 2034 or 2039, including any patent term adjustment, extensions or disclaimers, and the U.S. applications, if granted, are expected to have patent terms that expire in 2039 and 2040.

We also rely upon trade secret rights to protect our product candidates as well as other technologies that may be used to discover, validate and commercialize our current or any future product candidates. We presently seek protection, in part, through confidentiality and proprietary information agreements.

Trademarks

We hold a domestic registration for the trademark Daré Bioscience and our registration for the XACIATO trademark in the U.S. is pending. In accordance with the terms of the ADVA-Tec license agreement, we are the exclusive licensee of the Ovaprene registered trademark.

Competition

We are solely focused on women's health. Women's health is a broad category that encompasses health conditions that are unique to women, as well as conditions that affect both men and women, but that may affect women differently. Women's health products include drug, medical device, cosmetic and dietary supplement products, and generally are products designed for post-pubescent females. The women's health sector is very fragmented, highly competitive and subject to rapid and significant change. We anticipate that our product candidates may compete not only with FDA-approved, prescription and over-the-counter, branded and generic drug products, but also compounded drug products, medical devices, dietary supplements, and cosmetics. We face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies and specialty pharmaceutical companies that already possess a significant share of the women's health market, as well as generics manufacturers, compounding pharmacies and other drug compounding facilities, and dietary supplements manufacturers. In addition, academic and other research institutions are and could be engaged in research and development efforts for products in the therapeutic areas targeted by our product candidates. Our success is highly dependent upon our ability to acquire or in-license, develop and obtain regulatory approval for innovative products on a cost-effective basis and to market them successfully, either on our own or together with strategic partners, or to make our proprietary formulations available as compounded drugs. Many of our potential competitors have greater clinical, regulatory, manufacturing, marketing, distribution, compliance and financial

resources and experience than we do. See ITEM 1A. "RISK FACTORS—Risks Related to Commercialization of Products We Develop" and "Risks Related to 503B Compounding" below.

XACIATO competes directly with the multiple generic and branded prescription drug products currently approved in the U.S. for the treatment of bacterial vaginosis, including oral and vaginal gel formulations of metronidazole and vaginal cream formulations of clindamycin. As a result of our exclusive license agreement with Organon, the commercial success of XACIATO is outside of our control.

Our investigational contraceptive products, including Ovaprene, if approved, will compete with a wide range of prescription and over-the-counter contraceptive options, including hormone-free options such as condoms, diaphragms, cervical caps, sponges, copper intrauterine devices (IUDs), spermicides and vaginal gels, as well as hormonal products such as pills, patches, vaginal rings, IUDs, implantable rods and injectables. In addition, multiple new methods of pregnancy prevention are in development, including hormone-free options, and some may be marketed in the U.S. before Ovaprene, potentially adding to the level of market competition Ovaprene will face, if approved.

Currently, there are no FDA-approved therapies for FSAD. Sildenafil Cream has the potential to be the first FDA-approved product for the treatment of FSAD. However, Sildenafil Cream, if approved, may compete directly with compounded drugs available in the market, including those from outsourcing facilities that compound topical cream formulations of sildenafil citrate, the active ingredient in Sildenafil Cream. In addition, some compounding entities have partnered with telemedicine providers, enabling them to expand the potential market for their compounded drugs. The availability of other sildenafil products, could potentially make it more challenging for Sildenafil Cream to build and maintain market share.

If we are successful in bringing our proprietary Sildenafil Cream formulation to market under Section 503B of the FDCA, it would compete directly with other topical cream formulations of sildenafil citrate provided by compounding entities described above. However, our proprietary Sildenafil Cream formulation, as of the filing date of this report, to our knowledge, would be the only compounded form of sildenafil citrate that has completed toxicology studies and Phase 1, and Phase 2 human clinical studies.

DARE-HRT1, if approved as a treatment for moderate to severe VMS due to menopause, will compete with the many products on the market targeted to or FDA-approved for the treatment of menopausal symptoms, including VMS. Such products include hormone therapies in the form of pills, patches and creams, some of which are FDA-approved products and others which are supplied by compounding entities, as well as non-hormonal products, including an FDA-approved medication (Veozah® (fezolinetant)) and dietary supplements. Both the supplement and the compounded hormone therapy markets are very significant. A considerable segment of the compounded hormone therapy market is comprised of compounded hormones in pellet form that are implanted under the skin as a non-daily alternative, which could be directly competitive with DARE-HRT. In addition, we are aware of non-hormonal drug products in development for the treatment of VMS, including elinzanetant, a dual neurokinin-1 and 3 (NK-1 and NK-3) receptor antagonist, for which Bayer submitted an NDA in August 2024, and is anticipated to launch in the second half of 2025. We expect the options for hormone therapy to continue to expand with time. We intend for DARE-HRT1, if approved by the FDA, to offer advantages to compounded hormone therapy products, including by providing a product with a well characterized safety and efficacy profile that will have been vetted by the FDA. We believe DARE-HRT1 has the potential to address a preference among some women and health care providers for bio-identical hormones delivered in a non-oral route, as well as offer convenience compared to existing FDA-approved hormone therapies in that one IVR is designed to deliver the bio-identical hormones together over 28 days without any daily intervention.

DARE-VVA1, if approved as a treatment for moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of GSM, will compete with other hormonal and non-hormonal products for the treatment of dyspareunia or other GSM symptoms. Such products include hormone therapies in the form of pills, patches and creams, some of which are FDA-approved products and others which are supplied by compounding entities, as well as non-hormonal products in the form of pills and vaginal inserts, such as FDA-approved Osphena® (ospemifene) oral tablet, which is a SERM, and Intrarosa® (prasterone) vaginal insert, which is a steroid. We believe that DARE-VVA1 has the potential to address a preference due to personal or medical reasons among some women and healthcare providers to avoid estrogen and/or treatments with active ingredients that are estrogen-like or can metabolize into estrogen.

Currently, there are no FDA-approved therapies for HPV-related cervical disease. DARE-HPV has the potential to be the first FDA-approved product for the treatment of genital HPV infection in women and/or CIN (also known as cervical dysplasia). Persistent HPV infections can progress to cervical cancer through a series of cervical

lesions. Currently, there are no FDA-approved therapeutic treatments for HPV infections and no non-surgical pharmaceutical intervention to treat CIN2+. Surgical procedures are performed to remove late-stage cervical lesions to prevent the development of cervical cancer. We are aware of other product candidates in development to treat HPV-related cervical diseases, including an investigational vaginal insert being developed by Antiva Biosciences as a topical treatment for high-grade cervical intraepithelial neoplasia (HSIL, CIN2+) and for high-risk HPV infection, which currently is being evaluated in two Phase 1/2 clinical trials. These candidates may complete development, achieve FDA approval and be marketed in the U.S. before DARE-HPV, potentially creating direct market competition for DARE-HPV, if approved.

Over the longer term, our ability, independently or otherwise, to successfully develop, manufacture, market, distribute and sell any approved products, expand their usage, or bring additional new products or compounded drugs to the marketplace will depend on many factors, including, but not limited to, FDA and foreign regulatory agency approval of new products and of new indications for existing products, changes in 503B compounding regulations, whether the drug substances in our proprietary formulations appear and remain on the FDA's list of bulk drug substances that may be used in 503B compounding, the actual and perceived efficacy and safety of our products or our proprietary formulations made available via 503B compounding (alone and relative to other treatment options), the degree of patent or other protection afforded to particular products, and coverage and reimbursement by third-party payors.

Many other organizations are developing drug products and other therapies intended to treat the same diseases and conditions for which our product candidates are in development, and the success of others may render potential application of our product candidates obsolete or noncompetitive, even prior to completion of its development.

Government Regulation

Governmental authorities in the U.S., at the federal, state and local level, and other countries extensively regulate the research, development, testing, manufacturing, labeling and packaging, storage, recordkeeping, advertising, promotion, import, export, marketing, and distribution, among other things, of pharmaceutical, medical device, and drug-device combination products. The process of obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, require the expenditure of substantial time and financial resources.

We and our third-party manufacturers, distributors and contract research organizations, or CROs, may also be subject to government regulation under other federal, state, and local laws, including the U.S. Foreign Corrupt Practices Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act, the Health Insurance Portability and Accountability Act, privacy laws and import, export and customs regulations, as well as comparable laws and regulations of other countries.

U.S. Government Regulation

In the U.S., the FDA, under the authorities granted to the agency by the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, subjects pharmaceutical and other regulated medical products to rigorous premarket review as well as post-marketing oversight and potential enforcement actions. Failure to comply with applicable U.S. requirements at any time during the product development or approval process, or after approval, may subject a company to a variety of administrative or judicial sanctions brought by the FDA and the Department of Justice, or DOJ, or other governmental entities, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending or future marketing applications;
- warning or untitled letters;
- withdrawal of an approval;
- imposition of a clinical hold;
- voluntary product recalls;
- seizures or administrative detention of product;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, civil penalties or criminal prosecution.

FDA Approval Process for Prescription Drugs

To obtain approval of a new drug product from the FDA, we must, among other requirements, submit extensive data supporting its safety and efficacy, as well as detailed information on the manufacture and composition of the drug and proposed product labeling and packaging. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our product candidates.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves some or all of the following key steps:

- completion of nonclinical studies, such as laboratory tests, potentially animal studies, and formulation studies, performed in compliance with FDA regulations for good laboratory practices, or GLPs, and other applicable regulations;
- design of a clinical protocol and its submission to the FDA as part of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to good clinical practices, or GCPs, to establish the safety and efficacy of the product candidate for its intended use;
- submission of an NDA to the FDA along with payment of the application user fee and FDA acceptance of that NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with current good manufacturing practices, or cGMP, in order to assure that the facilities, methods and controls are adequate to preserve the drug candidate's identity, strength, quality and purity;
- possible inspection of selected clinical study sites to confirm compliance with GCP requirements and data integrity; and
- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, if applicable, which must occur prior to any commercial marketing or sale of the drug product in the U.S.

Preclinical Studies

After a therapeutic candidate is identified for development, it enters the preclinical or nonclinical testing stage. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA to specify that nonclinical testing for drugs may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests. Nonclinical tests intended for submission to the FDA to support the safety of a product candidate must be conducted in compliance with GLP regulations and the United States Department of Agriculture's Animal Welfare Act, if applicable. A drug sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will include one or more clinical protocols detailing, among other things, the objectives of the clinical trial and the safety and effectiveness criteria to be evaluated.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical study subjects.

Human Clinical Trials in Support of an NDA

The clinical investigation of an investigational new drug is divided into three phases that typically are conducted sequentially but may overlap or be combined. The three phases are as follows:

Phase 1. Phase 1 includes initial clinical trials introducing an investigational new drug into humans and may be conducted in subjects with the target disease or healthy volunteers. These trials are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

Phase 2. Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the drug candidate for a particular indication or indications in subjects with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 trials are typically well controlled, closely monitored, and conducted in a relatively small number of subjects.

Phase 3. Phase 3 trials are typically large trials performed after preliminary evidence suggesting effectiveness of the drug candidate has been obtained. They are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling and product marketing approval. Phase 3 trials usually are conducted at geographically dispersed clinical study sites.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed.

A pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need. Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with the FDA's GCP requirements. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol, and any subsequent material amendment to the protocol, must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must report to the FDA serious and unexpected adverse reactions in a timely manner, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product or therapeutic candidate. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, via a clinical hold, or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects are being exposed to an unacceptable health risk. An institutional review board, or IRB, is responsible for ensuring that human subjects in clinical studies are protected from inappropriate study risks. An IRB at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the trial until completed and otherwise comply with IRB regulations. The IRB also may halt a study, either temporarily or permanently, for failure to comply with GCP or the IRB's requirements, or if the investigational new drug has been associated with unexpected serious harm to patients.

During the development of a new drug product candidate, sponsors are given opportunities to meet with the FDA at certain points; specifically, prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the new therapeutic.

Post-approval trials, sometimes referred to as “Phase 4” clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of “Phase 4” clinical trials.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Application Submission and FDA Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more indications. An NDA includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the product candidate’s chemistry, manufacturing, and controls, or CMC, and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act, or PDUFA, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for marketed prescription drug products. Fee waivers or reductions are available in certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the applicant is a small business submitting its first human therapeutic application for review. Congress is required to re-authorize the agency's user fee programs every five years, and current legislative provisions supporting the PDUFA program are set to expire on September 30, 2027.

Under the current PDUFA goals and policies agreed to by the FDA, the agency has ten months from receipt in which to complete its initial review of a standard NDA for a drug that is not a new molecular entity, and six months from the receipt date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and the sponsor’s process to respond to such inquiries. As a result, the NDA review process can be very lengthy. Most innovative drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDCA, commonly referred to as a traditional or "full NDA." In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or “reference” product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. Section 505(b)(2) enables the applicant to rely, in part, on the FDA’s prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate or reduce the need to conduct certain pre-clinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. The FDA may then approve the new product candidate for all or

some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

The FDA conducts a preliminary review of all NDAs it receives, whether submitted under Section 505(b)(1) or Section 505(b)(2), to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA has 60 days after submission of an NDA to conduct an initial review to determine whether it is sufficient to accept for filing. If the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile and whether the product is being manufactured in accordance with cGMP. During its review of an NDA, the FDA may refer the application to an advisory committee of independent experts for a recommendation as to whether the application should be approved. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical trials are not always conclusive, and the FDA or its advisory committee may interpret data differently than the NDA sponsor interprets the same data. The FDA may also re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

Before approving an NDA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving the NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements and to assure the integrity of the clinical data submitted to the FDA. To ensure cGMP and GCP compliance by its employees and third-party contractors, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

The FDA also may require the submission of a risk evaluation and mitigation strategy, or REMS, plan if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan. The FDA will not approve an NDA without a REMS plan, if required.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities where the drug product or its API will be produced and the clinical trial sites, the FDA will either issue an approval letter or, in some cases, a complete response letter, or CRL, that describes all of the specific deficiencies in the NDA identified by the agency. An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, the FDA nevertheless may ultimately decide that the NDA does not satisfy the regulatory criteria for approval.

Even if a drug product receives regulatory approval, the approval may be significantly limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as "Phase 4" clinical trials, designed to further assess a product's safety and effectiveness, and/or testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new

indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Programs to Facilitate and Expedite Development and Review of Certain New Drugs

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include, but are not limited to, fast track designation, QIDP designation, and priority review designation. The purpose of these programs is to provide important new drugs to patients earlier than could occur under standard FDA procedures for interacting with and responding to product sponsors during development and regulatory review.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. A drug that is designated as a qualified infectious disease product, or QIDP, is also eligible for fast track status. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process.

The Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, included the Generating Antibiotics Incentives Now Act, or the GAIN Act, which directed FDA to implement the QIDP designation program. The GAIN Act created incentives for the development of antibacterial and antifungal drug products for the treatment of serious or life-threatening infections. A therapeutic candidate designated as a QIDP is eligible for fast track designation, and the first marketing application submitted for a specific drug product and indication for which QIDP designation was granted will be granted priority review. A subsequent application from the same sponsor for the same product and indication will receive priority review designation only if it otherwise meets the criteria for priority review. As discussed further below under “New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension - Qualified Infectious Disease Product Exclusivity,” the GAIN Act also provides the possibility of a five-year exclusivity extension that is added to any other marketing exclusivity for which a QIDP-designated drug qualifies upon FDA approval.

Finally, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA’s goal for taking action on a marketing application from ten months to six months.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, QIDP designation, and priority review do not change the standards for marketing approval and may not ultimately expedite the development or approval process.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Post-Approval Requirements for Prescription Drugs

Following approval of a new drug product, the manufacturer and the approved drug are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities,

reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Moreover, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or an NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. In particular, securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled clinical trials to demonstrate the product’s safety and efficacy in the new indication. Even if such trials are conducted, the FDA may not approve any expansion of the labeled indications for use in a timely fashion, or at all.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and some state agencies, and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other requirements. Changes to the manufacturing process, specifications or container closure system for an approved drug product are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the NDA sponsor and any third-party manufacturers involved in producing the approved drug product. Accordingly, both sponsors and manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance and other aspects of quality control and quality assurance, and to ensure ongoing compliance with other statutory requirements of the FDCA, such as the requirements for making manufacturing changes to an approved NDA.

Accordingly, even after a new drug approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or the imposition of distribution or other restrictions under a REMS plan. Other potential consequences of regulatory non-compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws. The Prescription Drug Marketing Act of 1987, or PDMA, was the first federal law to set minimum standards for the registration and regulation of drug distributors by the states and to regulate the distribution of drug samples. Today, both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act, or DSCSA, was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandated resource-intensive obligations for pharmaceutical manufacturers, repackagers, wholesale distributors, and dispensers (primarily pharmacies) over a 10-year period that culminated in November 2023. It also replaced certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme, requiring uniform national standards for wholesale distribution and, for the

first time, for third-party logistics providers. In February 2022, the FDA released proposed regulations to amend the existing national standards for licensing of wholesale drug distributors by the states (which had been promulgated under the PDMA); to establish new minimum standards for state licensing third-party logistics providers; and to create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA. Most recently, the FDA announced a one-year stabilization period to November 2024 followed by trading partner-specific exemptions through specified dates in 2025, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of prescription drug products regulated by the FDA.

FDA Review and Approval of Medical Devices

Medical devices also are strictly regulated by the FDA in the United States. Under the FDCA, a medical device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." This definition provides a clear distinction between a medical device and other FDA-regulated products such as drugs. If the primary intended use of a medical product is achieved through chemical action or by being metabolized by the body, the product is usually a drug or biologic. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through the premarket notification, or 510(k), process, or approved by the FDA pursuant to a PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. As electronic and digital medical devices have become increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve health care and patient accessibility, FDA and other regulatory authorities have recognized that those same features also increase the risk of potential cybersecurity threats. These types of medical devices may be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device, and accordingly device manufacturers are responsible for identifying cybersecurity risks and hazards associated with their products. In recent years, the FDA has increased its scrutiny of this issue as part of the review and marketing authorization process for new medical devices; the agency also monitors reports of cybersecurity risks as part of its post-marketing device surveillance activities. In addition, as part of the Consolidated Appropriations Act for 2023, Congress created new premarket requirements for developers of "cyber devices," defined as medical devices that include software, connect to the internet, and contain any technological features that could be vulnerable to cybersecurity threats.

Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably assure their safety and effectiveness. Class I devices are those low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR; facility registration and product listing; reporting of adverse medical events and malfunctions; and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Most Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) process. Notably, the agency has issued a final rule called the Quality Management System Regulation, or QMSR, to harmonize the FDA's medical device current good manufacturing practice regulations with the International Organization for Standardization, or ISO, standard for device quality management systems (ISO 13485:2016). The effective date for the QMSR final rule is February 2, 2026. Until then, manufacturers are required to comply with QSR.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for most Class II devices is accomplished through the 510(k) process, although some Class II devices are exempt from the 510(k) requirements. To obtain 510(k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent to a device that is already legally marketed in the United States and for which a PMA was not required (i.e., a Class II device). The device to which the sponsor's device is compared for the purpose of determining substantial equivalence is called a "predicate device." The FDA's goal is to make a substantial equivalence determination within 90 days of FDA's receipt of the 510(k) application, but it often takes longer if the FDA requests additional information. Most 510(k)s do not require supporting

data from clinical trials, but such data is typically required if the predicate device relied in part on clinical trial data to obtain clearance. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly a pre-market approval. Premarket notifications are subject to user fees, unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk to patients, such as life-sustaining or life-supporting devices, devices that present a potential unreasonable risk of illness or injury, or, more generally, devices whose safety and effectiveness cannot be assured solely by the general controls and special controls described above. All Class III devices must be reviewed and approved by the FDA through the PMA process. A PMA must be supported by extensive data including, but not limited to, technical data, nonclinical studies, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is submitted and the FDA determines the application is sufficiently complete, the agency will accept it for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, it considers such recommendations when making final decisions on approval. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. New PMA applications or supplements are also required for product modifications that affect the safety and efficacy of the device. PMA (and supplemental PMAs) are subject to significantly higher user fees than are 510(k) premarket notifications.

Novel medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they ultimately pose to patients and/or users. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *De Novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II based on a benefit-risk analysis demonstrating the device actually presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Today, as a result of certain amendments to the FDCA, manufacturers may request *De Novo* classification from the FDA without first submitting a 510(k) premarket notification and receiving a not substantially equivalent determination. The FDA is required under the statute to classify the device within 120 days following receipt of the *De Novo* application, however, the most recent FDA premarket review goals state that in fiscal year 2024, FDA will attempt to issue a decision on 80% of all *De Novo* classification requests received within 150 days of receipt. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. *De Novo* classification requests are also subject to user fees, unless a specific exemption applies.

Clinical trials are almost always required to support a PMA application and are sometimes required for a *De Novo* classification request or 510(k) premarket notification. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, an investigator acting on behalf of the company must, among other things, apply for and obtain IRB approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the company sponsoring the investigation must also submit and obtain FDA approval of an IDE. An IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of study participants, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE is approved by the FDA and the study protocol and informed consent form are approved by a duly-appointed IRB at each clinical trial site. A diversity action plan will be required for most clinical studies of investigational medical devices intended to support marketing authorization as a result of the December 2022 FDCA amendments.

FDA's IDE regulations govern investigational device labeling, prohibit promotion, and specify an array of GCP requirements, which include, among other things, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by

the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

Post-Marketing Requirements for Medical Devices

After a medical device is placed on the market, numerous regulatory requirements apply that in some ways mirror the post-approval requirements for prescription drugs. These include, but are not limited to:

- submitting and updating establishment registration and device listings with the FDA;
- compliance with the QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- pre-scheduled or unannounced device facility inspections by the FDA;
- labeling regulations, which prohibit the promotion of devices for uncleared or unapproved (or "off-label") uses and impose other restrictions relating to promotional activities;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any distributed devices fail to meet established specifications, are otherwise misbranded or adulterated, or if any other material deficiency is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

As with prescription drugs, the failure to comply with applicable device regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA approvals of new or modified devices;
- withdrawals of marketing authorization; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, prescheduled or unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors and third-party component suppliers.

FDA Review and Approval Process for Combination Products

A combination product is a product composed of a combination of two or more FDA-regulated product constituent parts or products, e.g., drug-device or biologic-device. Such products often raise regulatory, policy and review management challenges because they integrate constituent parts that are regulated under different types of regulatory requirements and by different FDA Centers, namely, the Center for Drug Evaluation and Research, or CDER, the Center for Devices and Radiological Health, or CDRH, or the Center for Biologics Evaluation and Research, or CBER. Differences in regulatory pathways for each constituent part can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprising two or more regulated constituent parts that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The FDA's Office of Combination Products, or OCP, was established to provide prompt determination of the FDA Center with primary jurisdiction over the review and regulation of a combination product; ensure timely and effective premarket review by overseeing the timeliness of and coordinating reviews involving more than one center; ensure consistent and appropriate post-market regulation; resolve disputes regarding review timeliness; and review/revise agreements, guidance and practices specific to the assignment of combination products.

OCP determines which Center will have primary jurisdiction for the combination product, referred to as the Lead Center, based on the combination product's "primary mode of action," or PMOA. A mode of action is the means by which a product achieves an intended therapeutic effect or action. The PMOA is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. The Lead Center has primary responsibility for the review and regulation of a combination product; however a second Center is often involved in the review process, especially to provide input regarding the "secondary" component(s). In most instances, the Lead Center applies its usual regulatory pathway. For example, a drug-device combination product assigned to CDER will typically be reviewed under an NDA, while a drug-device combination product assigned to CDRH is typically reviewed under through a 510(k), PMA, or *De Novo* classification request.

Often it is difficult for OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which Center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product. A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute, to obtain a binding decision as to which Center will regulate the combination product. If the sponsor objects to that decision, the sponsor may request that OCP reconsider its decision.

Combination products are subject to FDA user fees based on the type of application submitted for the product's premarket approval or clearance. For example, a combination product for which an NDA is submitted is subject to the NDA fee under PDUFA. Likewise, a combination product for which a PMA is submitted is subject to the PMA fee under the Medical Device User Fee and Modernization Act.

Since a combination product incorporates two or more constituent parts that have different regulatory requirements, a combination product manufacturer must comply with all cGMP and QSR requirements that apply to each constituent part. The FDA has issued a combination product cGMP regulation, along with final guidance, describing two approaches a combination product manufacturer may follow to demonstrate compliance. Under these two options, the manufacturer demonstrates compliance with: (1) All cGMP regulations applicable to each separate

regulated constituent part included in the combination product; or (2) either the drug cGMP or the QSR, as well as with specified provisions from the other of these two sets of requirements (also called the "streamlined approach"). In addition, The 21st Century Cures Act, or the Cures Act, amended the FDCA to clarify that for drug-device combination products with a device PMOA and an FDA-approved drug constituent part, Hatch-Waxman Act requirements apply. Accordingly, a potential patent dispute regarding the listed drug that is being referenced by the combination product sponsor may delay the marketing authorization of the combination product. Furthermore, the Cures Act amendments applied Hatch-Waxman Act exclusivity provisions (e.g., new chemical entity and new clinical investigation) to the device clearance and approval process for combination products with a device PMOA.

New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension

Orange Book Listing & Patent Certification

As noted above, Congress created the 505(b)(2) NDA pathway in 1984 as part of the Hatch-Waxman Act amendments to the FDCA. At the same time, it also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD. Unlike the ANDA pathway, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies to demonstrate safety or effectiveness of the proposed change(s) being made to a previously approved drug.

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in the Orange Book. Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant's product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or a 505(b)(2) NDA that relies in full or in part on the reference product. Patents for drug-device combination products that are listed in the Orange Book have recently come under scrutiny by the Federal Trade Commission, and the controversy regarding the appropriateness of listing such patents has led to numerous lawsuits alleging anticompetitive conduct by biopharmaceutical companies.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the ANDA applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator's listed patents, FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the

new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA/505(b)(2) applicant.

Non-Patent Exclusivity

An ANDA or 505(b)(2) NDA also will not be approved until any applicable non-patent exclusivities listed in the Orange Book for the referenced product have expired. The Hatch-Waxman Act amendments to the FDCA provided a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of data exclusivity if an NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, an applicant submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Qualified Infectious Disease Product Exclusivity

Under the GAIN Act amendments to the FDCA, the FDA may designate a product as a QIDP for a specific use for which it is being studied, upon the written request of a sponsor at any time prior to submission of a marketing application. In order to qualify for designation as a QIDP, the drug product candidate must qualify as an antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (i) an antibiotic or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (ii) a so-called "qualifying pathogen" found on a list of potentially dangerous, drug-resistant organisms established and maintained by the FDA. In addition to the expedited review benefits that a QIDP-designated drug candidate may be eligible for (described above under "Special FDA Programs to Facilitate and Expedite Development and Review of Certain New Drugs"), such a drug that is approved for the use for which the QIDP designation was granted will receive a five-year extension to any non-patent marketing exclusivity period for which the drug qualified upon approval, such as a five-year NCE exclusivity or three-year new clinical data exclusivity. This so-called GAIN exclusivity extension is not available to a QIDP-designated drug that has previously received the five-year extension period, such as when an applicant is seeking approval for a new indication or new strength for a marketed infectious disease product.

Patent Term Extension

A patent claiming a prescription drug or medical device for which FDA approval is granted may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug or medical device is under regulatory review while the patent is in force. The restoration period granted on a patent covering a

new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the marketing approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs and medical devices, are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against clinical trial sponsors that fail to comply with such requirements.

Other U.S. Health Care Laws and Compliance Requirements

As we plan to commercialize our product candidates, if approved, we are subject to additional health care statutory and regulatory requirements and enforcement by federal government and the states and foreign governments in the jurisdictions in which we conduct our business. Health care providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Arrangements we may enter into with third-party payors or other customers expose us to broadly applicable fraud and abuse and other health care laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval.

Violations of the fraud and abuse laws, or other health care laws, are punishable by criminal and civil sanctions, including, in some instances, the possibility of exclusion from participation in federal and state health care programs, (including Medicare and Medicaid), and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers, employees or consultants of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions under some of the fraud and abuse laws described below. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and extensive enforcement of them by law enforcement authorities. Further, federal and state laws that require manufacturers to make reports on pricing and marketing information could subject us to penalty provisions.

These applicable health care industry laws include, among others, health care information and data privacy and security laws, transparency laws, and fraud and abuse laws, such as:

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, providing, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with

health care companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;
- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal, civil and criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- The Physician Payments Sunshine Act, enacted as part of the ACA (defined below), among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non-physician health care practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members in such manufacturers;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations impose specified requirements relating to the privacy, security and electronic exchange of individually identifiable health information (called "protected health information" under HIPAA) as well as requirements for notification to affected individuals and the government in the event of a breach. Among other things, HITECH makes certain of HIPAA's privacy and all of HIPAA's security standards directly applicable to “business associates,” defined as independent contractors or agents of "covered entities," or organizations subject to HIPAA which include certain health care providers, health plans, and health care clearinghouses. Business associates create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and created penalties for third parties that unlawfully acquire protected health information. HITECH also gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions; and
- State and local laws which require the registration of pharmaceutical sales representatives.

The majority of states also have statutes or regulations similar to the aforementioned federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. We may be subject to state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus expanding and complicating compliance requirements. In addition, we may be subject to reporting requirements under state transparency laws, as well as state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to health care providers and entities.

To the extent we commercialize or co-promote our products, if approved, and because such products could be reimbursed under federal and other governmental health care programs, we have developed an appropriate compliance program, commensurate to the limited commercial activities in which we engage, that establishes internal controls to facilitate adherence to the rules and health care program requirements. Although compliance programs and adherence thereto may mitigate the risk of violation of and subsequent investigation and prosecution for violations of the laws described above, the risks cannot be eliminated entirely. Ensuring that our current and future business arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other health care laws and regulations. Moreover, if any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Coverage, Pricing, and Reimbursement

Sales of our drug and drug-device combination products, if approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health care programs, private health insurers, managed health care providers, and other organizations. These third-party payors are increasingly challenging drug prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approval as a benefit under their plans or, even if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved prescription products, including coding, coverage and payment. Sales of any products for which we obtain marketing approval will depend in part on coverage and adequate payment from third-party payors. There is no uniform policy requirement for coverage and reimbursement for prescription products among third-party payors in the United States; therefore coverage and reimbursement for prescription products can differ significantly from payor to payor.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. One third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Accordingly, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate payment will be applied consistently or granted at all. The process for determining whether a payor will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for health care providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use.

Additionally, the containment of health care costs has become a priority of federal and state governments and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2022, President Biden signed into the law the Inflation Reduction

Act of 2022, or the IRA, which includes (among other things) multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drug products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS is negotiating drug prices annually for a select number of single source Part D drugs without generic competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities, entering into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023 and ultimately announcing the first round of negotiated prices for the first 10 drugs in August 2024; those negotiated "maximum fair prices" will be effective as of January 1, 2026 (payment year 2026). CMS is currently engaged in its second round of negotiations and published the next 15 drugs selected for negotiation in January 2025. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future.

We expect that federal, state and local governments in the U.S. will continue to consider legislation directed at lowering the total cost of health care. Individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that has led to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements, including in the current 2025-2026 congressional session. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including medical product developers like us.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, has had and is expected to continue to have a significant impact on the health care industry. The ACA, among other things, imposes a significant annual fee on certain companies that manufacture or import branded prescription drug products. The ACA also increased the Medicaid rebate rate and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations. The ACA also expanded the 340B drug discount program (excluding orphan drugs), including a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, and revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of the Medicaid drug rebates paid to states. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against health care fraud and abuse, add new transparency requirements for the health care industry, impose new taxes and fees on pharmaceutical manufacturers, and impose additional health policy reforms. Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future.

It is uncertain whether and how future legislation or regulatory changes could affect prospects for our product candidates or what actions federal, state, or commercial payors for pharmaceutical products may take in response to any such health care reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates.

Regulation of Compounded Drugs

Drug compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a customized medication.

Compounded drugs are regulated at the federal level primarily under Sections 503A and Section 503B of the Federal Food, Drug, and Cosmetic Act, or the FDCA, which we refer to as Section 503A and Section 503B, respectively.

As discussed above, we are seeking to make our proprietary Sildenafil Cream formulation available by prescription as a compounded drug via Section 503B.

The term “outsourcing facility” refers to a facility that produces compounded drugs in accordance with Section 503B and distributes them either pursuant to a patient-specific prescription or in response to an order from a health care provider, such as a hospital, that is not for an identified individual patient (e.g., for office stock). Outsourcing facilities must be registered with the FDA and are subject to cGMP requirements and FDA inspections. In addition, an outsourcing facility must meet other conditions described in Section 503B, including reporting adverse events, labeling compounded products with certain information, reporting specific information about the drugs that it compounds, including a list of all of drugs it compounded during the previous six months, and the FDA-registered source of the active ingredients used to compound pursuant to Section 503B(b)(2). Under Section 503B, outsourcing facilities are prohibited from selling compounded drugs through a wholesale distributor, subject to certain exceptions set forth in FDA guidance.

Under Section 503B, outsourcing facilities are prohibited from compounding a drug that is “essentially a copy” of an FDA-approved drug, unless the drug is on the FDA’s Drug Shortage List at the time of compounding, distribution, and dispensing. A drug is essentially a copy of an FDA-approved drug if it is identical or nearly identical to the FDA-approved drug, which the FDA has interpreted to mean that it has the same active ingredient(s), route of administration, dosage form, dosage strength and excipients as the approved drug, or if it has the same active ingredient as an approved drug and there is not a change from the approved drug that produces a clinical difference for an individual patient, as determined by the prescribing practitioner.

Outsourcing facilities may only compound using bulk drug substances that either appear on a list established by the FDA of bulk drug substances for which there is a clinical need or drug products on FDA's Drug Shortage List. Although the FDA has not yet finalized its list of bulk drug substances for which there is a clinical need, the FDA has announced an interim policy pursuant to which bulk drug substances may be nominated for inclusion on such list and, provided certain conditions are met, outsourcing facilities may compound with such bulk drug substances pending evaluation of the substances for inclusion on the FDA’s list of bulk drug substances for which there is a clinical need. Sildenafil citrate is currently listed in FDA's interim Category 1 List of bulk substances that have been nominated, reviewed by FDA, and may be compounded by outsourcing facilities pending FDA’s final evaluation.

In December 2023, the FDA issued Guidance for Industry addressing the criteria by which the FDA intends to evaluate whether there exists a clinical need for compounding with a bulk drug substance.Under such guidance, the FDA intends to use a two-part analysis if the bulk drug substance is a component of an FDA-approved product, and if the bulk drug substance is not a component of an FDA-approved product, then the FDA intends to use only part 2 of such analysis. Under part 1 of the analysis, the FDA intends to evaluate whether there is a basis for the FDA to conclude that (a) an attribute of the FDA-approved drug that makes it medically unsuitable to treat certain patients; and the drug proposed to be compounded is intended to address that attribute; and (b) the drug proposed to be compounded must be produced from a bulk drug substance rather than from the FDA-approved drug product. If the answer to either of such questions is "no," then the FDA could determine that there is no clinical need for compounding with the bulk drug substance. If the answer to both such questions is "yes," then the FDA intends to proceed to part 2 of the analysis. Under part 2 of the analysis, the FDA intends to conduct a balancing test under which FDA would consider each of the following factors: (i) the physical and chemical characterization of the bulk drug substance; (ii) any safety issues raised by the use of the bulk drug substance in compounding; (iii) the available evidence of effectiveness or lack of effectiveness of a drug product compounded with the bulk drug substance, if any such evidence exists; and (iv) current and historical use of the bulk drug substance in compounded drug products, including information about medical condition(s) that the substance has been used to treat and any references in peer-reviewed medical literature. FDA has not announced when it will complete its analysis of nominated bulk substances and make a determination of substances that will be placed, after notice and a comment period, on FDA's final list of bulk substances that may be used in compounding by outsourcing facilities.

The source of any bulk substance active ingredient used in compounding must be a Section 510 registered manufacturer, and the bulk substance must be accompanied by a Certificate of Analysis.

Section 503A of the FDCA exempts licensed pharmacists or licensed physicians who compound drugs for identified, individual patients, based on the receipt of a valid prescription order, from the FDCA’s new drug approval requirements, cGMP requirements, and the requirement to label products with adequate directions for use, provided

certain conditions are met. These conditions include that the pharmacist or physician does not compound regularly or inordinate amounts any drug that is essentially a copy of an FDA-approved drug. The framework for assessing if a drug is essentially a copy of an FDA-approved drug under Section 503A is different than the framework under Section 503B described above. For instance, a Section 503A pharmacy may compound a formulation that is greater than 10% in dosage strength than the commercially available drug product, if that formulation is accompanied by a statement of significant difference. In addition, the substances that may be used in compounding under Section 503A are much broader than under Section 503B, because Section 503A pharmacies may compound from bulk substances that are components of FDA-approved drug products and substances that are the subject of a USP/NF monograph.

Sections 503A and 503B also prohibit compounding of drugs that present "demonstrable difficulties for compounding." The FDA must publish a list of such drugs, through notice and comment rulemaking, before implementing the prohibition, and FDA has not yet finalized any such lists for publication.

Data Privacy and the Protection of Personal Information

We are subject to numerous laws and regulations governing data privacy and the protection of personal information of patients, clinical investigators, employees, and vendors/business contacts including in relation to medical records and other health information, credit card data and financial information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy of health and personal information and federal and state consumer protections laws that regulate the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties as well as reputational harm. Our customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA, HITECH and state health information privacy laws. If we knowingly obtain protected health information without the authority to do so, our customers or research collaborators may be subject to enforcement and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act, or the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The FTC and states' Attorneys General have brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has adopted the California Consumer Privacy Act of 2018, or CCPA, which went into effect in January of 2020. The CCPA mirrors a number of the key provisions of the European General Data Protection Regulation, or GDPR, described below. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, requiring covered companies to provide new disclosures to consumers about such companies' practices for collection and use of consumer data, and providing customers new ways to opt-out of certain sales or transfers of personal information. In addition, the CCPA creates a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. More recently, a new privacy law, the California Privacy Rights Act, or CPRA, was approved by California voters in the election on November 3, 2020. The CPRA went into effect in January of 2023, modifying and strengthening the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which will be enacting new regulations and will have expanded enforcement authority. Various states such as Colorado,

Connecticut, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah and Virginia have enacted their own privacy laws similar to the CCPA, and other states are considering proposals for such.

Health Care Reform and Potential Changes to Laws and Regulations

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates that receive marketing approval. FDA and other regulatory authority policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. In addition to the sweeping reforms contained in the ACA (summarized above in the section entitled “Coverage, Pricing, and Reimbursement”), other legislative changes have been proposed and adopted in the United States that may affect health care expenditures.

Other new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on customers for our approved product and, accordingly, our financial operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services. Moreover, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Government Regulation Outside the U.S.

In addition to regulations in the U.S., we may be subject to a variety of regulations in foreign jurisdictions that govern, among other things, clinical trials and any commercial sales and distribution of our products, if approved, either directly or through our distribution partners. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical trials or marketing and sale of the product in those countries. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above, and the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Some foreign jurisdictions have a drug product approval process similar to that in the U.S., which requires the submission of a clinical trial application much like the IND prior to the commencement of clinical studies. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country’s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country’s requirements, clinical trial development may proceed. To obtain regulatory approval of a therapeutic product candidate under European Union, or EU, regulatory systems, we would be required to submit a Marketing Authorisation Application, which is similar to the NDA, except that, among other things, there are country-specific document requirements. For countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, and recently the United Kingdom, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Moreover, some nations may not accept clinical studies performed for U.S. approval to support approval in their countries or require that additional studies be performed on natives of their countries. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or any future partner of ours. If we fail to comply with applicable

foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

International marketing and distribution of medical devices are also subject to foreign government regulations, which may vary substantially from country to country. There is a trend towards harmonization of quality system standards for medical device products among the European Union, United States, Canada and various other industrialized countries.

As of January 31, 2020, the United Kingdom is no longer a member state of the EU, and therefore a separate marketing authorization application and approval will be required to market a medicinal product in the U.K. The Medicines and Healthcare products Regulatory Agency is the U.K.'s standalone pharmaceutical and medical devices regulator.

Review and Approval of Medicinal Products in the European Union

As in the United States, medicinal products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Also similar to the United States, when a drug-device combination product's principal intended action is accomplished by the drug constituent part, the EU regulates the combination product as a medicinal product.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU had been implemented through national legislation of the member states. Under the previous system, an applicant obtained approval from the competent national authority of an EU member state in which the clinical trial was conducted. Furthermore, the applicant could only start a clinical trial after a competent ethics committee had issued a favorable opinion. In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted and became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal" called the Clinical Trial Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials. Use of the CTIS became mandatory for new clinical trial application submissions as of February 1, 2023.

To obtain marketing approval of a drug in the EU, an applicant must submit a marketing authorization application ("MAA") either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, Iceland, Lichtenstein and Norway. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of certain diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the European Medicines Agency ("EMA") is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use ("CHMP"). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

The decentralized procedure is available to applicants who wish to market a product in specific EU member states where such product has not received marketing approval in any EU member states before. The decentralized procedure provides for an applicant to apply to one-member state to assess the application (the reference member state) and specifically list other member states in which it wishes to obtain approval (concerned member states). Under this procedure, an applicant submits an application based on identical dossiers and related materials, including

a draft summary of product characteristics, and draft labelling and package leaflet, to the reference member state and each concerned member state. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application which is then reviewed and approved commented on by the concerned member states. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

In the EU, only products for which marketing authorizations have been granted may be promoted. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Moreover, even if authorized to be marketed in the EU, prescription-only medicines may only be promoted to health care professionals, not the general public. All promotion should be in accordance with the particulars listed in the summary of product characteristics. Promotional materials must also comply with various laws, and codes of conduct developed by pharmaceutical industry bodies in the EU which govern (among other things) the training of sales staff, promotional claims and their justification, comparative advertising, misleading advertising, endorsements, and (where permitted) advertising to the general public. Failure to comply with these requirements could lead to the imposition of penalties by the competent authorities of the EU member states. The penalties could include warnings, orders to discontinue the promotion of the drug product, seizure of promotional materials, fines and possible imprisonment.

Prior to May 26, 2021, the date on which the new Medical Device Regulation ("MDR") became effective, medical devices marketed in Europe were required to comply with the Essential Requirements defined in Annex I to the EU Medical Devices Directive, or MDD, a coordinated system for the authorization of medical devices. The MDD regulated the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives. The method of assessing conformity depended on the class of the product, but normally involved a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product.

In 2017, European Union regulatory bodies finalized the MDR, which provided three years for transition and compliance, for a final effective date of May 26, 2020. As a result of the COVID-19 pandemic, however, the implementation date was postponed by one year to May 26, 2021, and a further transition period until May 26, 2024 gives the medical device industry and Notified Bodies additional time to come into compliance. The MDR changed several aspects of the existing regulatory framework for medical device marketing in Europe and increased regulatory oversight of all medical devices marketed in the EU, which may, in turn, increase the costs, time and requirements that need to be met in order to place an innovative or high-risk medical device on the European market. Specifically, the MDR requires post-market clinical follow-up evidence for medical devices, annual reporting of safety information for Class III products, and bi-annual reporting for Class II products, unique device identification, or UDI, for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, reclassification of medical devices, and multiple other labeling changes. A CE certificate issued under the MDD before May 26, 2021 may remain valid until May 25, 2024 under certain conditions. Longer transition periods for various medical devices covered by certificates or declarations of conformity issued before May 26, 2021 were implemented by the European Commission in March 2023 in order to mitigate the risk of device shortages in the EU. The new transition periods permit devices certified in accordance with the MDD to remain on the market under such certifications until May 26, 2026 for class III implantable custom-made devices, December 31, 2027 for Class III and implantable class IIb devices, and December 31, 2028 for all other class IIb and lower risk devices. As a new market entrant, however, the transition provisions do not apply to our business and we must acquire approvals under the MDR for new products, which could be challenging and costly.

Review and Approval of Medicinal Products in Canada

Health Canada is the Canadian federal authority that regulates, evaluates and monitors the safety, effectiveness, and quality of drugs, medical devices, and other therapeutic products available to Canadians. Health Canada's regulatory process for review, approval and regulatory oversight of products is similar to the regulatory process conducted by the FDA. To initiate clinical testing of a drug candidate in human subjects in Canada, a CTA must be filed with and approved by Health Canada. In addition, all federally regulated trials must be approved and monitored by research ethics boards. The review boards study and approve study-related documents and monitor trial data.

Prior to being given market authorization for a drug product, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act (Canada) and its associated regulations, including the Food and Drug Regulations. This information is usually submitted in the form of a New Drug Submission, or NDS. Health Canada reviews the submitted information, sometimes using external consultants and advisory committees, to evaluate the potential benefits and risks of a drug. If after of the review, the conclusion is that the patient benefits outweigh the risks associated with the drug, the drug is issued a Drug Identification Number ("DIN"), followed by a Notice of Compliance ("NOC"), which permits the market authorization holder (i.e., the NOC and DIN holder) to market the drug in Canada. Drugs granted an NOC may be subject to additional postmarket surveillance and reporting requirements.

All establishments engaged in the fabrication, packaging/labeling, importation, distribution, and wholesale of drugs and operation of a testing laboratory relating to drugs are required to hold a Drug Establishment License to conduct one or more of the licensed activities unless expressly exempted under the Food and Drug Regulations. The basis for the issuance of a Drug Establishment License is to ensure the facility complies with cGMP as stipulated in the Food and Drug Regulations and as determined by cGMP inspection conducted by Health Canada. An importer of pharmaceutical products manufactured at foreign sites must also be able to demonstrate that the foreign sites comply with cGMP, and such foreign sites are included on the importer's Drug Establishment License.

Regulatory obligations and oversight continue following the initial market approval of a pharmaceutical product. For example, every market authorization holder must report any new information received concerning adverse drug reactions, including timely reporting of serious adverse drug reactions that occur in Canada and any serious unexpected adverse drug reactions that occur outside of Canada. The market authorization holder must also notify Health Canada of any new safety and efficacy issues that it becomes aware of after the launch of a product.

The Canadian regulatory approval requirements for new drugs outlined above are similar to those of other major pharmaceutical markets. While the testing carried out in Canada is often acceptable for the purposes of regulatory submissions in other countries, individual regulatory authorities may request supplementary testing during their assessment of any submission. Therefore, the clinical testing conducted under Health Canada authorization or the approval of regulatory authorities of other countries may not be accepted by regulatory authorities outside Canada or other countries.

Health Canada has also implemented a similar process as the FDA for regulating combination products comprising both drug and device constituent parts. The agency considers the principal mechanism of action by which the claimed effect or purpose of the product is achieved, and then subjects the entire product to regulation under either the Food and Drug Regulations or the Medical Devices Regulations.

Rest of the World Regulation

In addition to regulations in the United States, EU, and Canada, we may become subject to a variety of regulations governing clinical studies and commercial sales and distribution of prescription drug and drug-device combination products in other jurisdictions around the world. These laws and regulations typically require the licensing of manufacturing and contract research facilities, carefully controlled research and testing of product candidates and governmental review and approval of results prior to marketing therapeutic product candidates. Additionally, they may require adherence to the FDA's GLPs, GCPs, and cGMPs during manufacturing. The process of new drug approvals by regulators in the United States, Canada and the European Union are generally considered to be among the most rigorous in the world.

Whether or not FDA, EMA, or Health Canada approval is obtained for a product, we must obtain approval from the comparable regulatory authorities of other countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for the FDA, EMA, or Health Canada approval. The requirements governing the conduct of

clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In some international markets, additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

Moreover, outside of the United States, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. In some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Europe – Data Privacy

On May 25, 2018, the GDPR went into effect, implementing a broad data protection framework that expanded the scope of EU data protection law, including to non-EU entities that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of European Union-based data subjects including: providing expanded disclosures about how their personal data will be used; limitations on retention of personal data, higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; requirements to conduct data protection impact assessments for "high risk" processing; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be “forgotten” and rights to data portability, as well as enhanced current rights (e.g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as “special category” data under the GDPR and afforded greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions – including restrictions – on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the EU member states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states’ laws and regulations, including where permitted derogations from the GDPR are introduced.

We will also be subject to evolving EU laws on data export, if we transfer data outside the EU to ourselves or third parties outside of the EU. The GDPR only permits exports of data outside the EU to countries deemed by the European Commission to have adequate data privacy laws or where there is a suitable data transfer solution in place to safeguard personal data (e.g., the European Union Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the European Union or the CJEU, issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II*. This decision a) calls into question certain data transfer mechanisms as between the EU member states and the U.S. and b) invalidates the EU-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the U.S.

On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the *Schrems II* decision. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the U.S. along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under the GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the transfer of personal data from the EU to us in the United States will require greater scrutiny and assessments as required under *Schrems II* and may have an adverse impact on cross-border transfers of personal data, or increase costs of compliance.

The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. We will be subject to the GDPR when we have a European Union presence or "establishment" (e.g., EU based subsidiary or operations), when conducting clinical trials with EU based data subjects, whether the trials are conducted directly by us or through a vendor or partner, or offering approved products or services to EU-based data subjects, regardless of whether involving a EU based subsidiary or operations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain health care professionals in many countries, either directly or through third parties. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Environmental, Health and Safety Regulation

We are subject to numerous federal, state and local environmental, health and safety, or EHS, laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our research laboratories. Some of these laws and regulations also require us to obtain licenses or permits to conduct our operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development and manufacturing activities involve use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure that EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

Employees

As of March 28, 2025, we had 23 employees. Twenty one of our employees are full-time and two are part-time, 17 are in research and development and six are in general and administrative. Given the differing characteristics of our product candidates, our approach is to engage consultants with experience in varying specialties to help us develop such candidates. Our numerous consultants serve as an extension to our employee base. We believe this approach enables us to access the expertise needed in a cost-efficient manner and without the need to rapidly increase the number of full-time employees and their associated costs. In the future, if we select a commercialization strategy for a product candidate that requires us to establish marketing, sales or distribution infrastructure and capabilities, we may need to rapidly increase our employee base.

Company Information

We were incorporated in Delaware in December 2005. Until July 2017, our corporate name was Cerulean Pharma Inc., or Cerulean. In July 2017, Cerulean completed a business combination with Daré Bioscience Operations, Inc., at which time we changed our name to "Daré Bioscience, Inc." and began to focus on development of innovative, investigational products in women's health. We and our wholly-owned subsidiaries operate in one business segment.

Available Information

Our website is located at *http://www.darebioscience.com*. Information found on our website is not incorporated by reference into this report. We make our filings with the U.S. Securities and Exchange Commission, or SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments and exhibits to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, available free of charge on or through our website, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings at *http://www.sec.gov*.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. We urge investors to carefully review and consider the additional discussion of the risks summarized in this risk factor summary, and other risks that we face, which can be found below under the heading "Risk Factors," together with other information in this report, before making investment decisions regarding our securities.

- We will need to raise substantial additional capital to continue our operations, execute our business strategy and remain a going concern, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all. Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights in our technologies or product candidates and their future revenue streams.
- If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.
- We have a limited operating history, a history of significant losses from operations, and expect significant losses from operations, net losses and negative cash flows from operations to continue for the foreseeable future, which, together with our limited financial resources, make it difficult to assess our prospects.
- We plan to generate revenue from sales of our proprietary Sildenafil Cream formulation produced under Section 503B of the FDCA. We have no experience in this line of business and may not succeed in our efforts. We will rely on third parties for the compounding and distribution of our proprietary Sildenafil Cream formulation, and the failure of such third parties to perform as expected could harm our reputation and negatively impact our ability to succeed. In addition, this line of business subjects us to new regulations and potential liability.
- Our business depends on obtaining the approval of regulatory authorities, and in particular, FDA approval, to market products that we develop. All of our product candidates are investigational, require the conduct and successful completion of clinical studies and nonclinical work, and may never complete development or be submitted for or receive regulatory approval. The FDA's approval of XACIATO is not predictive of favorable development or marketing approval outcomes for our product candidates.
- Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully complete clinical trials and nonclinical activities and obtain regulatory approval to market and sell our product candidates on our anticipated timelines at reasonable costs to us, or at all, particularly Ovaprene and Sildenafil Cream, could have a material adverse effect on our business, operating results and financial condition.
- The regulatory approval processes of the FDA and comparable foreign authorities are expensive, lengthy, time-consuming, and inherently unpredictable. If we are not able to obtain regulatory approvals for our product candidates, our ability to generate product revenue will be materially impaired.
- We rely on in-license agreements with third parties for rights to develop and commercialize XACIATO and our product candidates. The loss or impairment of our rights under these agreements could disrupt or require us to discontinue development or commercialization activities, or impair our rights to receive payments from our sublicensees, which could have a material adverse effect on our operations and business prospects and viability.
- Strategic collaborations are a key part of our strategy and our existing strategic collaborations are important to our business. If we are unable to maintain existing strategic collaborations or establish new ones, or if they are not successful, we may require substantial additional capital to develop and commercialize our products and product candidates and our business and prospects may be materially harmed.
- Delays and disruptions in the supply and manufacturing of our product candidates could postpone the initiation of or interrupt our clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and adversely impact the commercialization of any approved products.
- We have no manufacturing, sales, marketing or distribution infrastructure. We depend heavily on, and expect to continue to rely on, the performance of third parties, including our strategic collaborators, contract manufacturers and suppliers, CROs, medical institutions, and scientific, medical, regulatory and other consultants and advisors, to develop our product candidates and commercialize any approved products.

Failure of these third parties to perform as expected could result in substantial delays, increased costs or failures of our product development programs, delayed or unsuccessful commercialization of any approved products, and the need for significant additional capital.

- Due in part to our limited financial and human resources, we may fail to effectively execute our product development, regulatory submission and commercialization plans in accordance with communicated timelines, or at all.
- The commercial success of XACIATO is outside of our control and will depend on Organon's efforts and capabilities and a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our reputation, business and prospects may suffer.
- Our product candidates, if approved for commercial sale, will face intense competition and may fail to achieve the degree of market acceptance necessary for commercial success. Our business, operating results and financial condition will suffer if we, or our commercial collaborators, fail to compete effectively.
- Failure to successfully obtain coverage and adequate reimbursement for XACIATO and any future products from government health care programs and other third-party payors would diminish our ability, or that of a commercial collaborator, to generate net product revenue or net sales. If out-of-pocket costs for products we develop are deemed by women to be unaffordable, a commercial market may never develop.
- We have a relatively small number of employees and if we fail to attract and retain key personnel our business may materially suffer.
- We may not be successful in our efforts to identify and acquire or in-license additional product candidates or technologies, which may limit our growth potential.
- If we and our licensors are unable to obtain and maintain sufficient intellectual property protection, competitors could develop and commercialize or make available products similar or identical to ours, which could significantly limit the commercial potential of our products and product candidates and materially harm our business, financial condition, results of operations, and prospects.
- Most of the products we are developing utilize active pharmaceutical ingredients that are not proprietary to us or our licensors and the patents and patent applications owned by us and our licensors intended to protect our products and product candidates relate to specific formulations, processes, methods of delivery, and/or uses, which may not afford sufficient protection against competitors.
- Volatility in the financial markets, geopolitical conflicts and events, natural disasters, public health emergencies , international trade policies,and other macroeconomic factors may negatively impact our business, financial condition and results and our stock price, including by increasing the cost and timelines for our clinical development programs or making it more difficult or costly to raise additional capital when needed.
- Product liability lawsuits against us could cause us to incur substantial liabilities and divert management attention from our business.
- The price of our common stock has been and may continue to be highly volatile and such volatility may be related or unrelated to our performance and operating results. Volatility in our stock price may subject us to increased risk of securities litigation, including class-action lawsuits, which could be expensive and divert management attention.
- Future dilution to our existing stockholders from sales and issuances of our common stock to raise additional capital, or the market's expectation that such sales may occur, could adversely affect our stock price even if our business is doing well.
- We have been subject to a cyber-related crime and our controls and security measures may not be successful in preventing other cybersecurity incidents in the future. Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our strategic collaborators or third-party service providers could compromise sensitive or confidential information related to our business, delay or prevent us from accessing critical information, subject us to significant financial loss, or expose us to liability, any of which could adversely affect our business and our reputation.

Risk Factors

Investment in our securities involves a high degree of risk and uncertainty. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this report and our other public filings, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Needs

We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.

We have a history of losses from operations, we expect significant losses from operations, net losses and negative cash flows from operations for at least the next several years as we develop and seek to bring to market our existing product candidates and as we seek to potentially acquire or license and develop additional product candidates. At December 31, 2024, we had an accumulated deficit of approximately $175.3 million, cash and cash equivalents of approximately $15.7 million, and a working capital deficit of approximately $3.2 million. We will need additional capital to fund our operating needs into the third quarter of 2025 and to meet our current obligations as they become due. All of our cash and cash equivalents at December 31, 2024 represented funds received under grant agreements that generally may be applied solely toward direct costs of carrying out the respective projects under those grant agreements. We have a history of losses from operations and we expect significant losses from operations, net losses, and negative cash flows from operations for at least the next several years as we continue to develop and seek to bring to market our product candidates. We are dependent on securing substantial additional capital from one or more third-party sources to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. These circumstances raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements included in this report were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. Advancing our investigational products through clinical development and pursuing regulatory approval and commercialization will require substantial additional investment. We will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. The amount and timing of our capital needs have and will continue to depend highly on many factors, as discussed further below.

Our management may devote significant time and we may incur substantial costs in pursuing, evaluating and negotiating potential capital-raising transactions and those efforts may not prove successful on a timely basis, or at all. If we cannot raise adequate additional capital when needed, we may be forced to reduce, or even terminate our operations. We may delay, scale back or eliminate one or more of our product development programs; relinquish rights under our license agreements with third parties relating to our product candidates; forgo opportunities to expand our product portfolio; take other measures to reduce our expenses; reorganize or merge with another entity; or file for bankruptcy or cease operations. For example, in recent years, due to our limited capital resources, we have focused our resources primarily on the advancement of Ovaprene and Sildenafil Cream, unless a program has been supported by grant or other non-dilutive funding, and we have delayed R&D activities for other programs. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and our stockholders may lose all or part of their investment in our common stock.

Our capital needs have depended on, and will continue to depend on, many factors that are highly variable and difficult to predict, including:

- the product development programs we choose to pursue;
- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our product candidates that we are pursuing or may choose to pursue in the future;
- the cost and timing of manufacturing for clinical supplies of product candidates and, if applicable, commercial product at sufficient scale;
- the cost and timing of regulatory submissions to and the timing and outcome of decisions by the FDA and other regulatory authorities on our applications to commence and advance clinical development of and to market our product candidates;
- the amount and timing of payments to third parties required under acquisition, in-license and other agreements relating our rights to develop and commercialize our product and product candidates;
- the cost and timing of commercialization activities we undertake or engage third parties to undertake for any product;
- the amount and timing of future royalty, milestone or other payments, if any, we receive under our licensing agreement with Bayer, any future out-licensing agreement, or the Royalty Purchase Agreements;
- our ability to maintain, and establish new, strategic collaborations relating to the development and/or commercialization of our product and product candidates, and the terms and timing of such arrangements;

- the extent to which we acquire, in-license, or otherwise invest in new product candidates or technologies and the terms of any such transaction; and
- the cost and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights.

Should we add product candidates to our portfolio, should our existing product candidates require testing or other capital-intensive development activities that we do not anticipate, should the duration of our clinical trials be longer than anticipated, should manufacturing and supply be disrupted, or should regulatory approvals be delayed, our cash resources will be further strained. Should our product development efforts succeed, we will need to develop and implement a commercialization plan for each product, which may also require significant resources to create and implement. In addition, the terms of any collaboration agreements for development and/or commercialization of our product and product candidates may significantly impact our need for additional capital. Because of these uncertainties and the other risks and uncertainties discussed in this Risk Factors section, we cannot reasonably estimate the amount funding necessary to successfully complete development of and seek regulatory approval for our product candidates or to commercialize any approved products. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our planned operations.

We may seek to raise additional capital through a variety of means, including equity, equity-linked or debt securities offerings, government or other grant funding, strategic collaborations or alliances, debt, royalty monetization or other structured financings, or other similar types of arrangements. Our past success in raising capital through equity offerings, grant funding, collaboration agreements, and royalty monetization transactions should not be viewed as any indication we will be successful in raising capital through those or any other means in the future. We expect that our ability to raise additional capital and the amount of capital available to us will depend not only on progress we and our collaborators make toward successfully developing, obtaining regulatory approval for and commercializing our product and product candidates, but also on factors outside of our control, such as macroeconomic and financial market conditions. To the extent we seek to obtain additional capital before achieving clinical, regulatory and/or sales milestones or when our stock price or trading volume or both are low, or when the general market for biopharmaceutical or women's health companies is weak, additional capital may not be available to us on favorable terms, or at all.

Unstable and unfavorable market and economic conditions may harm our ability to raise additional capital. The occurrence or continued occurrence of macroeconomic factors or events similar to those experienced in recent years, such as a U.S. economic crisis or recession or recessionary concerns, inflation, rising interest rates, public health emergencies (such as the COVID-19 pandemic), geopolitical conflict (such as the wars in Ukraine and the Middle East), natural/environmental disasters, supply-chain disruptions, terrorist attacks, strained trade and other relations between the U.S. and a number of other countries, social and political discord and unrest in the U.S. and other countries, and government shutdowns, among others, increase market volatility and have long-term adverse effects on the U.S. and global economies and financial markets. Volatility and deterioration in the financial markets and liquidity constraints or other adverse developments affecting financial institutions may make equity or debt financings more difficult, more costly or more dilutive and may increase competition for, or limit the availability of, funding from other third-party sources, such as from strategic collaborations and government and other grants.

Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights in our technologies or product candidates and their future revenue streams.

As discussed above, we may seek to raise additional capital through a variety of means. Raising capital through the issuance of shares of our common stock, or securities convertible into or exercisable for our common stock, may depress our stock price and substantially dilute our existing stockholders. The terms of securities issued may include liquidation or other preferences that may materially adversely affect the rights of our existing stockholders. Debt and other structured financings, if available, would increase our fixed payment obligations and may involve covenants requiring us to maintain specified financial ratios or a specified cash balance, or limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, or impose other operating restrictions that could adversely impact our ability to operate our business and pursue our strategic objectives. We could also be required to meet certain milestones in connection with a debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies, product candidates or products, or otherwise agree to terms unfavorable to us. In addition, we may forego part or all of potentially valuable streams of future payments (e.g., milestone and/or royalty revenue) to raise immediate capital to fund our operations and advance our development programs, such as in the case of our royalty interest financing agreement and the Royalty Purchase

Agreements. Moreover, the lower our cash balance when we seek to raise additional capital, the more difficult, costly or dilutive to our existing stockholders it may be for us to raise additional capital.

We may be required to seek additional capital through arrangements with collaborators at an earlier stage of development or commercialization of our technologies, product candidates or products than otherwise would be desirable, in which case we may grant rights to our technologies, product candidates or products on terms that may not be as favorable to us or grant rights that we would otherwise prefer to retain. If we raise capital through new collaborations, strategic alliances or other similar types of arrangements, we may relinquish valuable rights to future revenue streams. Licensing agreements likely would significantly reduce our control over the development or commercialization of the licensed technology, product candidates or products, and our collaborators may become unable or unwilling to devote adequate resources to realize their full potential value. If we obtain funding through grants from governmental entities or private organizations, such parties may impose restrictions on our rights to technologies, product candidates or products developed with such funding, obtain rights to license such technologies, product candidates or products to third parties (e.g., if we are unable or unwilling to commercialize a product or make it available to certain patient populations in a timely manner or at certain prices), or require future royalty or other payments if such technologies, product candidates or products are commercialized.

We have a limited operating history, a history of significant losses from operations, and expect significant losses from operations, net losses and negative cash flows from operations to continue for the foreseeable future, which, together with our limited financial resources, make it difficult to assess our prospects.

We have a limited operating history upon which to evaluate our business and prospects. The development of drug and drug/device combination products in order to obtain regulatory approval is a highly speculative, lengthy and expensive undertaking and involves substantial risk. We cannot accurately determine the duration and completion costs of our development programs, or if, when and to what extent we will generate revenue from any products we develop. Other than XACIATO, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue. We have not been profitable since we commenced operations and may never achieve profitability. We devote significant resources to licensing or otherwise acquiring the rights to our product candidates and to research and development, or R&D, activities for them. We have a history of significant operating losses. As discussed above, we must raise additional capital to finance our operations and remain a going concern and adequate additional capital may not be available to us on a timely basis, or at all.

The Revenue Sharing Threshold may never be achieved and, as a result, we may not realize any future income based on sales of XACIATO.

We have sold our right, title and interest in 100% of the royalties and potential milestone payments we would otherwise have the right to receive under our license agreement with Organon based on net sales of XACIATO, net of payments to upstream third-party licensors and UiE. Whether we receive any future income based on net sales of XACIATO will depend on whether the Revenue Sharing Threshold is reached, which may not occur. Whether the Revenue Sharing Threshold is reached will depend, in part, on Organon's future commercial success with XACIATO, which is outside of our control, and the successful development and commercialization of Ovaprene and/or Sildenafil Cream, which are subject to significant risks and uncertainties, some of which are outside of our control, as discussed elsewhere in this Risk Factors section.

To the extent we enter into licensing agreements for third-party commercialization of products we develop, as is the case with XACIATO and Ovaprene, we expect our revenue streams related to those products will be based primarily on net sales, which will be largely outside of our control.

In a typical biopharmaceutical licensing or "partnering" deal, the biopharmaceutical company out-licenses technology and other assets to a third party in exchange for future payments, the bulk of which (e.g., royalties and milestones) are conditional on the licensee successfully developing and/or commercializing the licensed assets and determined based on net sales. To the extent we enter into such licensing agreements, the amount of net sales our products may generate, if approved for commercial sale, will be largely outside of our control because marketing and sales activities will be conducted by the licensee and product pricing and costs that impact net sales will be determined by the licensee. Gross sales can be greatly reduced by sales discounts and allowances, which will be determined by our licensee (or mandated by governmental entities). Sales discounts may be particularly substantial for new products compared to established products to incentivize purchases and promote customer loyalty. These factors would serve to reduce the royalties payable to us and delay potential achievement of commercial milestones and the corresponding milestone payments to us. If a licensee has no or limited commercialization success, or net sales are otherwise minimal due to pricing and discount structures, our financial condition and operating results could be negatively impacted and our need for additional capital could significantly increase or be accelerated. Due to our

exclusive license agreements with Organon and Bayer, assuming the license grant to Bayer becomes effective, our royalty interest financing agreement, and the Royalty Purchase Agreements, XACIATO's and Ovaprene's value to us will be based primarily on net sales, as determined under those agreements.

In the future, we may rely on revenues received from third-party licensees to fund our operations, and failure to receive such revenues, or receipt of only minimal revenue, may cause us to, among other things:

- pursue raising additional funds through equity, debt or other structured financings that could be dilutive to our stockholders or involve restrictive covenants, operational restrictions, security interests in our assets, and/or relinquishing part or all of our rights to potentially valuable future revenue streams;
- enter into new strategic collaborations that may be less favorable than those we would have obtained under different circumstances;
- delay, reduce or terminate one or more development programs;
- reduce headcount;
- forgo opportunities to expand our product portfolio; or
- take other measures to reduce our expenses, pursue strategic transactions, such as a merger or other business combination or sale of assets, file for bankruptcy, or cease operations.

If one of our commercial collaborators terminates its exclusive license agreement with us, our need for additional capital may significantly increase.

We have entered into an exclusive license agreement with Organon for the commercialization of XACIATO and an exclusive license agreement with Bayer for the commercialization of Ovaprene, if approved for commercial sale. Each of these license agreements may be terminated by the licensee for convenience upon the completion of a specified notice period, subject to limited restrictions. Furthermore, under our agreement with Bayer, Bayer has no payment obligations to us, unless, after reviewing the results of our pivotal clinical trial of Ovaprene, it elects, in its sole discretion, to make the license grant under our agreement effective by making a $20.0 million payment to us. If we do not successfully complete a pivotal clinical trial of Ovaprene in a timely manner, the license grant may never become effective, and we may not receive any additional payments from Bayer. Bayer may elect not to make the license grant effective regardless of the outcome of the pivotal clinical trial. If an exclusive license agreement is terminated early, or in Ovaprene's case, does not become fully effective, we may realize only a small fraction of the potential value of the agreement to us, and we would need to raise significant additional capital to pursue further development and commercialization of XACIATO or Ovaprene, as applicable, or establish another commercial collaboration, which we may not be able to do on a timely basis, on favorable terms, or at all.

We have relied heavily on sales of our common stock to fund our operations, and our ability to obtain additional capital through stock sales or other securities offerings may be more costly or dilutive to our stockholders than in the past, or may not be available to us at all. Our ability to raise additional capital may be limited by a low trading volume, stock price and market capitalization, as well as by laws, regulations and market conditions.

We have relied heavily on our ability to raise capital by selling shares of our common stock. For example, we raised an aggregate of approximately $79.1 million in gross proceeds in fiscal years 2021 and 2022 through the sale of shares of our common stock in offerings made under a Form S-3 "shelf" registration statement. Our ability to raise additional capital through sales of our common stock or other securities offerings will depend on several factors, many of which may not be in our favor, including the trading volume and volatile trading price of our common stock, our relatively low public float and market capitalization, our potential inability to regain and maintain compliance with the listing requirements of the Nasdaq Capital Market, unfavorable financial market conditions, and the other risks and uncertainties described in this Risk Factors section. If we are unable to raise additional capital through the offering and sale of shares of our common stock, or securities convertible into or exercisable for our common stock, on a timely basis or acceptable terms, or at all, we may seek additional capital through other third-party sources that require us to relinquish valuable rights in our intellectual property, technologies, product candidates or future revenue streams, or that subject us to restrictive covenants, operational restrictions or security interests in our assets, or we may need to delay, scale back or eliminate some or all of our development programs, reduce other expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Using a shelf registration statement to conduct an equity offering to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. We currently have a shelf registration statement effective, however, our ability to raise capital under a shelf registration statement is, and may continue to be, limited by, among other things, current and future SEC rules and regulations

impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. For example, we currently are subject to the "baby shelf rule" because the market value of our outstanding shares of common stock held by non-affiliates, or our public float, was less than $75.0 million at the time of filing this annual report on Form 10-K, calculated in accordance with SEC rules. This means that we may use our shelf registration statement to raise additional funds only to the extent that the aggregate market value of securities sold by us or on our behalf pursuant to Instruction I.B.6. of Form S-3 during the 12 calendar months immediately prior to, and including, the intended sale does not exceed one-third of the aggregate market value of our public float, calculated in accordance with the instructions to Form S-3. If our ability to offer securities under an effective shelf registration statement is limited, including by the baby shelf rule, we may choose to conduct an offering of our securities under an exemption from registration under the Securities Act or under a Form S-1 registration statement. We would expect either of these alternatives to take more time and be a more expensive method of raising additional capital relative to using our shelf registration statement.

In addition, under SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to use a Form S-3 registration statement (1) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or a re-evaluation date, whichever is later, and (2) to register the resale of our securities by persons other than us (i.e., a resale offering). While our common stock is currently listed on the Nasdaq Capital Market, there can be no assurance that we can maintain such listing. See, “Risks Related to Ownership of Our Common Stock—If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock,” below.

Our ability to raise capital on a timely basis through the issuance and sale of equity securities may also be limited by Nasdaq’s stockholder approval requirement for any transaction that is not a public offering (as defined in Nasdaq listing rules). For transactions other than public offerings, Nasdaq requires stockholder approval prior to the issuance or potential issuance of common stock (or securities convertible into or exercisable for common stock) at a price per share that is less than the "Minimum Price" if the issuance (together with sales by our officers, directors and substantial shareholders (as defined in Nasdaq listing rules)) would equal 20% or more of our common stock outstanding before the issuance. Under Nasdaq rules, the "Minimum Price" means a price that is the lower of (i) the Nasdaq official closing price immediately preceding the signing of the binding agreement; or (ii) the average Nasdaq official closing price of the common stock for the five trading days immediately preceding the signing of the binding agreement. In addition, certain prior sales of securities by us may be aggregated with any offering we may propose at a price that is less than the Minimum Price and which is not considered a public offering by Nasdaq, further limiting the amount we could raise in the offering. Under Nasdaq rules, stockholder approval is also required prior to the issuance of securities when the issuance or potential issuance will result in a change of control of our company. Even if a public offering under Nasdaq rules is not subject to the 20% limitation described above, it may involve publicly announcing the proposed transaction, which often has the effect of depressing the market price of a company's stock and could result in a reduced offering price. Accordingly, our existing investors may suffer greater dilution if we seek to raise additional capital through such a public offering of our securities.

Obtaining stockholder approval is a costly and time-consuming process. If we must obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our business plan, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, we may be unable to pursue and complete the clinical trials we would like to pursue and complete, and we may be unable to commence or complete clinical trials and pursue regulatory approvals in accordance with our current timeline expectations.

Our current financial and other resources are limited and not sufficient to develop all of the product candidates to which we hold licenses or options to license. This may affect our efforts to develop and bring to market the product candidates currently in our portfolio and any candidates we may add to our portfolio in the future. Due to our limited resources, we have curtailed, and may be required to further curtail, certain of our development programs and clinical and nonclinical development activities that might otherwise have led, or lead, to more rapid progress in the development of our product candidates, or product candidates that we may in the future choose to develop. We may make determinations with regard to the indications and clinical trials on which to focus our resources that result in our realization of less than the full potential value of a product candidate. The decisions to allocate our research,

management, personnel and financial resources toward particular indications may not lead to positive clinical milestones or to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also cause us to miss valuable opportunities, including the potential for some of our product candidates to be first-in-category products.

As a result of financial and other resource constraints, we may be unable to commence or complete our planned clinical trials or prepare and submit applications for marketing approval of our product candidates in accordance with our currently anticipated timelines. See also “Risks Related to Product Research & Development and Regulatory Approval – Delays in the commencement or completion of clinical testing of our product candidates may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable” below.

Women’s health has historically been an underfunded sector. In recent years, a number of public companies focused in women’s health failed to achieve expected commercial success and struggled to access sufficient capital. We are solely focused in women’s health and may be unfavorably impacted by weak investor sentiment and a lack of interest in the category. Our ability to access capital and to advance our candidates could be adversely impacted.

We are solely focused in women’s health, and primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease and menopause. The sector has historically been underfunded, with only about one percent of healthcare research and innovation in the U.S. invested in female-specific conditions beyond oncology according to market research. Non-oncologic women's health therapeutics product launches in recent years have not been perceived as successful. Those perceived commercial failures and the failure of the women’s health sector to receive consistent and committed investment fuels investor sentiment that market opportunities for new products in women’s health are limited. While women's health recently has received more attention, and investment in the women's health sector has seen progress with new or increased funding programs from the federal government, it remains an underinvested sector. Further, there is a high level of uncertainty regarding whether the federal government under the new U.S. presidential administration will continue programs initiated by the prior presidential administration that led to increased funding for research and development in women’s health. Our stock price and our ability to access additional capital on acceptable terms when needed may be adversely impacted by unfavorable investor perception of market opportunities for women’s health products, and our business, operating results, financial condition and prospects could suffer.

Uncertainty in U.S. federal government funding and contracting policies may adversely affect our business.

Changes in federal funding and contracting policies under the new U.S. presidential administration could materially impact the progress of certain of our development programs, including Ovaprene and DARE-HPV, as well as our operating results and financial resources. We have received federal government grants and awards in support of several of our development programs. As discussed elsewhere in this report, our pivotal Phase 3 study of Ovaprene is being conducted, in part, in collaboration with NICHD under our CRADA, and our DARE-HPV program is being supported in large part with funding provided by federal agencies. There is no guarantee that such contracts and funding will not be frozen, restricted, or terminated as a result of changes in federal funding and contracting policies. In addition, potential future funding and collaboration opportunities through HHS, NIH or other federal agencies may be delayed, reduced or made unavailable. Further, research and development conducted in collaboration with U.S.-based colleges and universities could be delayed or discontinued due to changes in federal funding and contracting policies relating to such institutions. These changes could adversely affect our development programs, financial condition, operating results and business plans.

Our cash could be adversely impacted if a financial institution with which we have deposit or other accounts fails.

Our cash and cash equivalents we use to satisfy our working capital and operating expense needs are held in accounts at various financial institutions. The balance held in deposit accounts often exceeds the Federal Deposit Insurance Corporation (“FDIC”) deposit insurance limit or similar government deposit insurance schemes. Our cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which we hold our cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation and taken into receivership by the FDIC. At that time, substantially all of our cash and cash equivalents were held in accounts with Silicon Valley Bank and we could not access such accounts. While we were afforded full access to our accounts on March 13, 2023 as a result of action taken by the U.S. Department of the Treasury, the Federal Reserve and the FDIC under the systemic risk exception, there is no guarantee that the systemic risk exception will be relied upon to provide access to

uninsured deposits and other assets in the future in the event of the closure of a financial institution, or that such access would be afforded in a timely fashion. Any loss of our cash or cash equivalents or any delay in our access thereto could, among other risks, adversely impact our ability to pay our operating expenses, result in breaches of our contractual obligations, or result in violations of federal or state wage and hour laws if we are unable to pay our employees on a timely basis.

Risks Related to Product Research & Development and Regulatory Approval

To date, XACIATO is the only FDA-approved product to emerge from our portfolio. The FDA's approval of XACIATO does not provide any assurance or predict that we will be successful in developing or achieving regulatory approval to market any other product candidate. If we are unable to successfully conduct and complete development of and obtain regulatory approvals for our investigational products, which may never occur, our business may fail and you could lose all or part of your investment.

Historical success in clinical development of and obtaining regulatory approval for a product candidate does not guarantee or predict future successful outcomes for other investigational products. Each of our development programs is unique and subject to substantial uncertainty of success inherent in pharmaceutical and biopharmaceutical development.

Our current pipeline consists entirely of investigational products, which we also refer to as product candidates, which means that they must successfully complete one or more clinical studies to be considered for marketing approval and undergo a submission and review process with the FDA to obtain approval to be marketed in the U.S., or a similar process with comparable regulatory authorities in other jurisdictions to be marketed anywhere outside of the U.S. FDA or other regulatory authority approval may never be obtained. See also ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products" and "–Government Regulation Outside the U.S." above. If we are unable to successfully complete development of and obtain regulatory approvals for our product candidates, our business may fail and you could lose all or part of your investment.

Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully develop and obtain regulatory approval to market and sell our product candidates, and in particular, Ovaprene and Sildenafil Cream, would likely adversely affect our business.

Our business depends on the successful clinical development and regulatory approval of our product candidates, and in particular, our lead product candidates, which may never occur. The product candidates we develop require substantial clinical testing to demonstrate that they are safe and effective for their proposed uses. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial. Accordingly, while some of our product candidates have undergone clinical trials and demonstrated positive results, including Ovaprene and Sildenafil Cream, there is no guarantee of successful outcomes in current or future clinical studies of these product candidates or of obtaining marketing approval for any of them. For example, while PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness and our PCT clinical trial of Ovaprene met its primary endpoint, there is no guarantee Ovaprene will demonstrate contraceptive effectiveness in its ongoing pivotal Phase 3 clinical study or demonstrate a level of contraceptive effectiveness that will enable it to compete effectively in the contraceptive market. As another example, while data from our exploratory Phase 2b RESPOND study of Sildenafil Cream allows us to advance Sildenafil Cream into Phase 3 development, the co-primary efficacy endpoints of the Phase 2b study were not met and there is no guarantee that our planned Phase 3 clinical studies, which will have the same co-primary efficacy endpoints used in the Phase 2b study, will be successful. The fact that the active pharmaceutical ingredients in certain of our product candidates, including Sildenafil Cream, received regulatory approval in other formulations and/or for other indications does not guarantee successful development of our product candidates for their proposed intended uses. Clinical trials may never demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates.

Outcomes of our clinical trials, particularly later-stage clinical trials, including our ongoing Phase 3 study of Ovaprene, may significantly impact our stock price and our business prospects. If interim, preliminary or final results from our clinical studies are not positive, or are perceived by third parties, including the medical community, current and potential collaborators, and the investment community, as not positive, our stock price could decline significantly, our reputation may suffer, and our ability to raise additional capital to continue to operate as a going concern and execute our business strategy could be adversely impacted. If a product candidate fails to demonstrate adequate

safety or effectiveness in a clinical study, we may determine to delay, scale back or terminate the program, and we may not realize any return on our investment in the program.

Even if we conduct and complete clinical trials for our product candidates, we may not obtain regulatory approval to market and sell any of them on the timelines we anticipate, or at all, which would have a material adverse effect on our business and operations.

Delays in the commencement or completion of clinical testing of our product candidates may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable.

Clinical trials of our product candidates may not commence, progress or be completed as expected. Delays could significantly impact our product development costs and timelines, as well as a product candidate's market potential, if ultimately approved. The timing of initiation, conduct and completion of clinical trials and other development activities for our product candidates may vary dramatically due to factors within and outside of our control and is difficult to predict accurately. We may make statements regarding anticipated timing of clinical development milestones, such as commencement, completion of enrollment, and/or availability of results from our clinical studies, but those statements are predictions based on significant assumptions and the actual timing of achievement of development milestones may differ materially from our predictions for a variety of reasons.

The commencement of clinical trials of our product candidates can be delayed for many reasons, including:

- lack of adequate capital and the need to obtain additional funding;
- delays in obtaining guidance or authorizations from the FDA or foreign regulatory authorities;
- delays in obtaining approval from the institutional review boards, or IRBs, of prospective clinical study sites;
- delays in finalizing the trial design as a result of discussions with the FDA, foreign regulatory authorities, prospective clinical trial investigators or IRBs;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites; or
- inability to obtain sufficient quantities of clinical product supplies from our contract manufacturers and suppliers.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us, an IRB, the FDA or other regulatory authorities as a result of the occurrence of any of a number of events or circumstances, including:

- lack of adequate capital and the need to obtain additional funding;
- failure to conduct the clinical trial in accordance with its protocol or regulatory or IRB requirements;
- slower than expected rates of participant recruitment and enrollment;
- higher than anticipated participant drop-out rates;
- failure of participants to use the investigational product as directed or to report data as per trial protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- failure to achieve certain efficacy and/or safety standards;
- participants experiencing severe undesirable side effects or other unexpected adverse events;
- disruptions in or insufficient supply of clinical trial material or inadequate quality of such materials;
- failure of our CROs or other third-party service providers to meet their contractual obligations to us in a timely manner, or at all; or
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

Unexpected SAEs or other undesirable side effects could arise during clinical development and interrupt, delay, or cause the termination of clinical trials, and require us to conduct additional clinical and nonclinical studies that were not part of our development plan, which could significantly increase the development costs and timeline for a program and adversely impact its value and our ability to continue product development. These events may also cause our reputation to suffer and subject us to lawsuits.

As discussed elsewhere in this Risk Factors section, macroeconomic factors and events also have the potential to cause or contribute to significant delays in commencement and completion of our clinical trials. Global supply chain disruptions and the subsequent effects thereof may adversely affect the ability of contract manufacturers to manufacture and supply our clinical trial material. Our prospective or contracted clinical trial sites may experience

resource constraints, including staffing shortages, stemming from global or regional issues, such as a public health emergency, natural disaster, or worker strike, and become unable to allocate adequate resources to reach agreements necessary to commence our clinical trials at their facilities or, even if agreements are in place, to conduct our clinical trials. For ongoing clinical trials, macroeconomic factors or events, such as a global pandemic, may result in lower than anticipated subject enrollment and completion rates, including because clinical trial sites may temporarily close or reallocate resources away from clinical research, or study participants may withdraw prior to receiving study treatment or discontinue their treatment or follow up visits to avoid medical settings or because they become sick or must care for a sick family member.

Significant clinical trial delays could have a material adverse impact on our financial condition and results of operations by substantially increasing the costs of our development programs. Significant clinical trial delays also could jeopardize our ability to meet obligations under agreements under which we license our rights to our product candidates, allow other companies to bring competitive products to market before we do, shorten any period of market exclusivity we may otherwise have under our patent rights, and weaken our negotiating position in discussions with potential collaborators, any of which could impair our ability to successfully complete development of or commercialize our product candidates, if ultimately approved. Any significant delays in commencement or completion of clinical trials of our product candidates, or the suspension or termination of a clinical trial, could materially harm our business, financial condition and results of operations.

Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products.

The manufacture of our product candidates is subject to compliance with extensive regulatory requirements, in some cases is complex, and in most cases we rely on single source contract manufacturers and suppliers. As a result, we face significant risks of manufacturing and supply delays and disruptions that may be difficult and expensive to resolve and may cause substantial delays in the development and regulatory approval of our product candidates or the commercialization of any approved product. To date, our clinical-stage product candidates have been tested in a relatively small number of clinical study participants. Significant scale-up of manufacturing will be required to provide adequate supplies of our product candidates for larger Phase 2 and Phase 3 clinical trials and may take longer and be more expensive than anticipated. For example, the ongoing pivotal clinical study of Ovaprene will require far more clinical product supplies than were manufactured for prior clinical and nonclinical studies combined. A substantial scale up in production of Ovaprene clinical supplies was necessary to support the ongoing Phase 3 clinical study of Ovaprene, which took longer and was more expensive than anticipated, impacting our development timeline. Under our agreement with ADVA-Tec, we are dependent on ADVA-Tec and its contract manufacturer, Poly-Med, Inc., for all Ovaprene clinical and commercial product supplies, and we do not control these third parties and have limited influence the efforts and resources they expend to meet our supply requirements. Disruptions and delays in scaling up manufacturing of our product candidates for later stage clinical studies may have a significant negative impact on our development costs and timelines. We have, and we expect we will continue to, face multiple challenges as our contract manufacturers scale their processes to provide supplies for larger clinical trials or commercial production including, among others, potential difficulties with process scale-up, process reproducibility, stability and purity issues, compliance with cGMP, lot consistency, and timely availability of acceptable raw materials.

The manufacture of our product candidates is subject to extensive regulation. The finished products (and their APIs) used in clinical trials or approved for commercial sale must be manufactured in accordance with cGMP requirements in the U.S. that are enforced by the FDA and must comply with applicable requirements of foreign regulatory authorities for sales outside of the U.S. These regulations govern manufacturing processes and procedures, including record keeping and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of a product that may result in closure of the manufacturing facility for an extended period of time to investigate and remedy the contamination or inadvertent change. In addition, deviations anywhere in the manufacturing process could cause our product candidates to perform differently and affect the results of clinical trials. Further, even minor deviations in the manufacturing process, including filling labeling, packaging, storage and shipping, and quality control and testing, may result in shipment delays, lot failures, recalls or spoilage, and delay or disrupt our clinical studies or commercial supply of any approved product. See also ITEM 1. “BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products” and “–Government Regulation Outside the U.S.” above. If our contract manufacturers are unable to produce sufficient quantities of our product candidates (or their APIs) for clinical trials or, if approved for commercial sale, for commercialization at acceptable quality levels, our

development and commercialization efforts would be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

As product candidates progress through the development process, it is not uncommon that manufacturing methods are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs, achieve consistent quality and results, or to comply with regulatory authority requirements. Any such changes carry risk that they will not achieve the intended objectives. If and when changes are made to the manufacturing process of our product candidates (or their APIs), we may be required by the FDA or foreign regulatory authorities to conduct bridging clinical or nonclinical studies or repeat one or more clinical trials to demonstrate comparable identity, strength, quality and purity of the product candidate before and after such changes, which could significantly increase development costs and delay regulatory approval or disrupt commercial supply. These manufacturing and supply risks are similarly applicable to any product or product candidate we license to a commercial collaborator and could adversely impact the timing or amount of potential milestone and royalty payments to us.

In addition, our cost of goods for our product candidates is at an early stage of development. The cost to manufacture our product candidates at commercial scale is difficult to predict currently. We may need to alter the materials, equipment or processes for making our product candidates in order to yield commercially viable products. As discussed above, manufacturing changes could increase development costs and timing, delay regulatory approval or disrupt commercial supply and may not achieve the intended objectives. Manufacturing costs may negatively impact the commercial viability of our product candidates, if approved for commercial sale.

See also “Risks Related to Our Dependence on Third Parties- We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third-party suppliers and manufacturers for clinical study materials, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, do not maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business,” and “- In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties, increase the risk of manufacturing disruptions, and result in higher development costs or costs of goods sold” below.

The factors contributing to female sexual dysfunction disorders, including FSAD, are complex and there is limited clinical trial precedent from which to draw experience, making the design and execution of a clinical trial that demonstrates effectiveness of Sildenafil Cream in treating FSAD more inherently challenging and uncertain compared with investigational products for many other conditions.

There are currently no FDA-approved pharmacologic treatments for FSAD and there is no precedent program to reference in the design of our clinical trials for Sildenafil Cream. Female sexual dysfunction disorders in women vary in nature and may be the result of a variety of physiological and psychological factors. Given the variability of factors contributing to the underlying condition, and the product candidates' attributes, clinical studies to evaluate effectiveness in any subset of the conditions under the umbrella of female sexual dysfunction, such as FSAD, are complex. While we worked with experts to select existing as well as develop novel patient reported outcome (PRO) instruments for our exploratory Phase 2b RESPOND study of Sildenafil Cream, tested the potential PRO instruments in a content validity study, reviewed the results of that study with the FDA and aligned with the FDA on the Phase 2b study design, there is no precedent program that has utilized these same endpoints in a Phase 3 study and there is no assurance they will be adequate to detect a treatment effect. In addition, the Phase 2b RESPOND study proved more difficult to enroll than anticipated given the enrollment criteria for the study, particularly the requirement that the partner be enrolled in the study. Moreover, the Phase 2b RESPOND study did not demonstrate statistical significance for the co-primary or secondary efficacy endpoints. While post-hoc analyses of data from the Phase 2b RESPOND study identified a subset of participants that achieved statistically significant improvement in one of the co-primary efficacy endpoints of the study and the planned Phase 3 study will be in that subset of patients, there can be no assurance that Sildenafil Cream will be successful in the planned Phase 3 study.

Sildenafil Cream is designed to work primarily by increasing blood flow to the genital tissue. Therefore, identifying and enrolling patients in our clinical trials of Sildenafil Cream for whom inadequate blood flow to the genital tissue is the primary contributor to their arousal disorder is critical. If we fail to screen study participants properly, the results of our clinical trials are unlikely to demonstrate effectiveness of Sildenafil Cream. Conversely, screening procedures may slow enrollment in a study, delay its completion and increase its costs. In our exploratory Phase 2b RESPOND study, we experienced a slower than anticipated pace of enrollment given the enrollment criteria for the study, which lengthened our original estimated timeline for the study. We may experience delays in future clinical studies of Sildenafil Cream relative to our communicated expectations due to the novel nature of the studies and the

complexities of the condition it is intended to treat, which may significantly lengthen clinical study timelines, increase overall costs, and may lead to unfavorable results.

With respect to any clinical study of Sildenafil Cream, even if we can identify and enroll a sufficient number of women for whom inadequate blood flow to the genital tissue is the primary contributing factor to their arousal disorder, there is no guarantee that the use of Sildenafil Cream will meaningfully improve their sensations of arousal or demonstrate statistically significant improvement in the primary or secondary efficacy endpoints of the study. We expect to conduct two Phase 3 studies to support an NDA for Sildenafil Cream. Given the multiple factors contributing to arousal disorders and the novelty of the clinical endpoints that will be utilized to measure effectiveness of Sildenafil Cream in treating FSAD, we may be required to conduct multiple clinical trials in large patient populations, extending the timeline and increasing the cost of development for Sildenafil Cream, without any guarantee of positive results. If we are unable to efficiently and successfully advance Sildenafil Cream through clinical development, our business, operating results and financial conditional, as well as our stock price, could suffer.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, and others, including regulatory authorities, may not agree with our interpretation of study data.

From time to time, we may publicly disclose interim, preliminary or topline data from our clinical studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results of clinical trials we report may differ from final results reported for those studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final, complete data are available.

Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. There can be no guarantee that a favorable interim analysis will result in a favorable final result at the completion of the clinical trial.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of study data differently than we do, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically an extensive set of data and analyses, and investors and others may disagree with the information we determine is the material or otherwise appropriate information to include in our public disclosure. Information we determine not to publicly disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate, product or our business. If the topline data that we report differ from complete results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our business depends on obtaining regulatory approval to market our product candidates in a timely manner, in particular, FDA approval. The regulatory approval processes of the FDA and comparable foreign authorities are expensive, lengthy, time-consuming, and inherently unpredictable. If we are not able to obtain regulatory approvals for our product candidates, our ability to generate product revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, release, safety, efficacy, regulatory filings, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, other regulatory authorities in the U.S., and comparable authorities in other countries or jurisdictions where we seek to test or market our product candidates. The process of obtaining marketing approvals in the U.S. and elsewhere is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. In addition, requirements for approval may change over time and our current development plans may not accurately anticipate all applicable requirements for marketing

approval by the FDA or comparable regulatory authorities for jurisdictions outside the U.S. See also ITEM 1. “BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products” and “–Government Regulation Outside the U.S.” above.

Our success depends on our ability to obtain regulatory approvals for our product candidates in a timely and cost-efficient manner. Even if we successfully complete nonclinical studies, clinical studies, manufacturing and other required activities, we may still experience delays in our efforts to obtain marketing approvals for any of our product candidates. Marketing approval applications require the submission of extensive clinical and nonclinical data and supporting information to establish the safety and efficacy of our product candidates for the specified indication. The process of responding to the FDA or other regulatory authorities’ information requests in the review process, potentially preparing for and appearing at a public advisory committee or oral hearing, and preparing our third-party manufacturers and clinical investigators to successfully complete inspections by the FDA or other regulatory authorities during the approval process requires significant human and financial resources.

We may change the development plan for a product candidate as a result of changes during the development period in the FDA’s marketing approval policies or the amendment or enactment of additional statutes or regulations, updated interpretations of applicable policies, statutes or regulations, or upon review of outcomes of other similar product candidates under development. This could significantly lengthen our development timelines and cost.

The FDA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional clinical or nonclinical studies or changes in the manufacturing process or facilities, even if we had previously aligned with the relevant regulatory authorities on such data and other requirements. We cannot assure you that we will obtain any additional marketing approvals for our product or product candidates in any jurisdiction.

The announcement of new requirements by the FDA, the failure of a competitive product to receive regulatory approval, or the receipt of a complete response letter from the FDA by another company pursuing the FDA's 505(b)(2) pathway for product candidates identical to or similar to ours, any of which may have implications for our proposed regulatory authorization pathways, could impact how investors and potential strategic collaborators view the development risks associated with our product candidates. Changing testing or manufacturing requirements for our product candidates or for product candidates deemed to be comparable to ours may adversely impact our financial resources, our development timelines and may harm the perception held by others of our business.

A change in the regulatory approval pathway we anticipate for a product candidate could significantly increase development cost and timeline and heighten the risk of failure.

We expect to utilize the FDA’s Section 505(b)(2) pathway for most of our current product candidates, including all of our clinical-stage candidates other than Ovaprene, and if that pathway is not available, the development of our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complexity and risk than currently anticipated, and, in any case, may not be successful.

Section 505(b)(2) of the FDCA permits the filing of an NDA in which the applicant relies, at least in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its NDA, potentially eliminating or reducing the need to conduct certain nonclinical testing or clinical studies and expediting development timelines relative to the traditional or "full" NDA under Section 505(b)(1) of the FDCA.See ITEM 1. “BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs– Marketing Application Submission and FDA Review” above for more information. If the FDA changes its 505(b)(2) policies and practices, if Congress were to amend the FDCA, or if the current 505(b)(2) pathway is otherwise not available for a product candidate as anticipated, we likely would need to conduct more clinical trials and nonclinical testing than planned to generate additional safety and efficacy data and other information to support an NDA. If this were to occur, the time and financial resources required to obtain FDA approval, as well as the development complexity and risk associated with these programs, would likely substantially increase, which could have a material adverse effect on our business and financial condition. In addition, Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505(b)(2) NDA, and the filing of a patent infringement lawsuit against us following our submission of a 505(b)(2) NDA could significantly delay any potential FDA approval of the NDA. Even if we are able to utilize the Section 505(b)(2) regulatory pathway for one or more of our candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval or commercial launch.

In regard to Ovaprene, a change in the FDA’s prior determination that CDRH would lead the review of a marketing application for Ovaprene would adversely impact Ovaprene’s development timeline and significantly raise our costs to complete clinical development and obtain regulatory approval. Ovaprene is composed of both device and

drug components and is considered a combination product by the FDA. The process for obtaining FDA approval of Ovaprene will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary. See ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Combination Products," above for more information about the FDA review and approval process for combination products. Ovaprene previously underwent a request for designation, or RFD, process with the FDA that determined that CDRH would lead the review of a PMA for potential marketing approval of this product candidate. If the designation were to be changed to CDER, or if either center were to institute additional requirements for the approval of Ovaprene, we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would significantly increase the anticipated cost and timeline to completion of Ovaprene's development and require us to raise additional funds. Based on discussions with the FDA, we believe that if our ongoing pivotal clinical study of Ovaprene is successful, the FDA will not require additional clinical studies to support the PMA for Ovaprene. However, the FDA may determine that the results of the study are not sufficiently robust or convincing and require additional clinical and/or nonclinical studies prior to approval of Ovaprene. Because Ovaprene is one of our lead product candidates, the impact of either a change in the lead FDA review center or the imposition of additional, currently unplanned requirements for approval could be significant to us and have a material adverse effect on the prospects for developing Ovaprene, as well as on our business and our financial condition.

If we are unable to pursue FDA approval via the FDA's 505(b)(2) pathway or, in the case of Ovaprene, through review of a PMA by CDRH, new competitive products may reach the market more quickly than our product candidates, which may have a material adverse impact on our competitive position and prospects. Even if we are allowed to pursue the FDA's 505(b)(2) pathway, and in the case of Ovaprene, review of a PMA by CDRH, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Some of our product candidates may be considered combination products by the FDA and other regulatory authorities, which could increase the complexity, cost and timeline for their development and regulatory approval.

To the extent our product candidates meet the FDA's or any other regulatory authority's definition of a combination product, the regulatory approval requirements can be more complex and costly because, in addition to the individual regulatory requirements for each component, e.g., a drug and a medical device, additional combination product regulatory requirements may apply. See ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Combination Products," above. The cost and timeline for development of product candidates determined to be combination products may be substantially greater than product candidates that are not considered combination products.

Our clinical-stage product candidates have only been tested in a small number of women over short periods of use and no data exists regarding a potential increase in fetal abnormalities in pregnant women.

If our clinical-stage product candidates, including Ovaprene and Sildenafil Cream, are successful in their clinical development, we expect that women of child-bearing age will use them, and potentially for many months or years. To date, human clinical studies of these product candidates have been for relatively short periods of time and these product candidates lack safety data over longer periods of use. For example, while we believe the risk of adverse fetal development from using these product candidates is low, the impact of these product candidates on fetal development has not been studied and there are no adequate or well-controlled studies of these product candidates in pregnant women. Thus, the risk of adverse fetal development from any one or more of these product candidates may be greater than expected. Should any of these product candidates be shown to increase the risk of adverse fetal development, our ability to develop those or other product candidates would be substantially impaired, our business prospects and operations could be materially harmed, and we could also be subject to potential claims and lawsuits.

Pre-clinical product candidates may be undervalued by investors and may be difficult to fund.

Given their early stage of development and the lack of data, many pre-clinical assets are often perceived as having low valuations by investors and potential strategic collaborators, such as pharmaceutical companies. Our investment of time and resources in such assets may not be appreciated or valued. As a result, it may be difficult for us to fund such programs. Additionally, past receipt of grant funding may not be predictive of our ability to secure additional grants to fund further development of a program. Our portfolio includes several pre-clinical stage programs

and if they fail to be adequately valued by investors or potential strategic collaborators, our business, financial condition and stock price may be adversely affected.

Several of our product candidates are in pre-clinical stages of development and may never advance to clinical development.

Pre-clinical studies refer to a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected. Because of their early nature, pre-clinical product candidates tend to carry a higher risk of failure as compared with clinical-stage assets. Pre-clinical candidates must generate sufficient safety and efficacy data through in vitro studies, animal studies and a variety of tests before they can be considered appropriate for testing in humans. The development risks, timeline and cost of pre-clinical assets can be high because of the unknowns and absence of data. It can be difficult to identify relevant tests and animal models for pre-clinical studies. Even if the results from our pre-clinical studies are favorable, we still may not be able to advance the candidates into clinical trials. If pre-clinical studies of product candidates do not generate strong data, our pre-clinical stage programs may never progress to clinical development and may prove to be worthless.

The grants and other non-dilutive funding awards supporting several of our development programs do not guarantee that the pre-clinical or clinical development work being funded will be successful or that we will be able or will choose to fund the additional development work that will be required in the future to advance the product candidates toward regulatory approval.

The grants and other non-dilutive funding supporting development of several of our programs, including Ovaprene, DARE-HPV, DARE-PTB1, DARE-LARC1, DARE-LBT, and activities to aid in the identification and development a novel non-hormonal intravaginal contraceptive candidate, should not provide any assurance that pre-clinical or clinical development supported by that funding will be successful, or, even if we are successful with all specified development activities, that we will be able or will choose to fund the additional development work that will be required to continue to advance the product candidates toward commercialization. Further, the grant agreements or other non-dilutive funding award agreements supporting these development programs generally feature milestone-based payments or, in the case of NIH grants, payments are received in reimbursement of specified activities, and there is no assurance that we will be able to achieve or otherwise demonstrate satisfaction of the specified development and reporting milestones required to receive future payments under the agreements. Additionally, the counterparties to these agreements may modify, suspend, discontinue payment of funds or terminate the agreements in certain circumstances largely in their discretion. Accordingly, we may never receive future payments under these agreements or realize the full potential amount of the grant or other funding award.

Risks Related to Our Dependence on Third Parties

Our existing product development and commercialization collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, if these collaborations are not successful, or if we are unable to establish additional strategic collaborations, our business and prospects may be materially harmed.

We have limited resources and no internal sales, marketing or distribution capabilities. A key aspect of our strategy is to establish collaborations with third parties, such as large and mid-size pharmaceutical companies and other third parties with the relevant R&D and/or commercial expertise and infrastructure, to help bring our product candidates to market. We currently do not expect to directly market, sell or distribute any of our products that receive regulatory approval, and instead intend to enter into agreements with third parties to market, sell and distribute and provide related support services for those products. For example, we have entered into out-license agreements with third parties for the commercialization of XACIATO and, if approved for commercial sale, Ovaprene. We intend to seek additional strategic collaborations. However, such strategic collaboration opportunities may not be available to us for a variety of reasons. For example, certain potential pharmaceutical company collaborators have announced discontinuation or significant reduction in their research and development efforts in women's health therapeutics. To the extent we do enter into strategic collaborations similar to our agreements for the commercialization of XACIATO and Ovaprene, the successful development and commercialization of our products and product candidates may become partially or entirely dependent upon the performance of third parties. By entering into strategic collaborations, we may relinquish control over important elements of product development and commercialization, and the collaborator may fail to develop or effectively commercialize the applicable products or product candidates. In addition, in the case of commercial collaborations, our product revenues may be lower than if we were to sell and distribute products that we develop ourselves.

Our existing collaborations, and any future strategic collaborations we establish, involve significant risks to the success of the product, including that:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development or commercialization of a product or product candidate or elect not to continue or renew a collaboration based on clinical or nonclinical study results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, a public health emergency, or macroeconomic events or conditions, that cause them to divert resources to other initiatives or create competing priorities;
- collaborators may refuse to perform clinical studies or other development work required for approval in a particular jurisdiction outside the U.S.;
- collaborators may delay or stop clinical studies, provide insufficient funding for or abandon a clinical program, repeat or conduct new clinical studies or require a new formulation of a product or product candidate for clinical testing;
- collaborators could independently, or together with third parties, develop and commercialize products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more of our products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or product development or commercialization strategy, might cause delays or termination of the research, development or commercialization of our products or product candidates, might lead to additional responsibilities for us with respect to products or product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may violate, or be investigated for potentially violating, health care compliance and related laws and regulations, which may expose us to litigation, enforcement actions or inquiries, or other potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, could significantly delay product development and commercial launch and increase the cost to us to pursue further development or commercialization of the applicable product or product candidate. For example, our out-license agreements for XACIATO and Ovaprene and the CRADA with NICHD may be terminated by the counterparty for convenience upon the completion of a specified notice period, subject to limited restrictions.

If a collaborator terminates its agreement with us or if a collaboration does not result in the successful development of any product candidates and/or commercialization of any approved products, we may not receive any future royalty revenue, commercial milestones or other revenues under the collaboration, our development programs may not be funded as we expect, and our ability to establish another collaboration for the applicable product or product candidate may be negatively impacted. We may be unable to replace any commercial collaborator with an alternate third party on a timely or commercially reasonable basis, or at all. See also, “Risks Related to Our Financial Position and Capital Needs- If one of our commercial collaborators terminates its exclusive license agreement with us or fails to perform as expected, our need for additional capital may significantly increase,” above and “We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our product development programs. Failure of these third parties to successfully carry out their contractual duties, comply with regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our development timelines and/or failure of our programs,” below. Moreover, the risks relating to product development, regulatory approval and commercialization and compliance with health care related laws and regulations described in this report also apply to the activities of our collaborators.

Organon has global commercial rights to XACIATO under our exclusive license agreement. There is no assurance that commercialization of XACIATO in the U.S. will be successful, or that Organon will pursue development and commercialization of XACIATO outside of the U.S. As discussed elsewhere in this Risk Factors section, as a result of the traditional royalty purchase agreement we entered into with XOMA, whether we receive any future income based on net sales of XACIATO will depend on whether the Revenue Sharing Threshold is reached, which will depend, in part, on Organon's future commercial success with XACIATO, which is outside of our control. Apart from Organon's diligence obligation under our license agreement, we have no control over the efforts and resources Organon devotes to the marketing and sale of XACIATO. The occurrence of any of the risks described above could negatively impact the commercial success of XACIATO and have a material adverse effect on our business, financial condition and results of operations.

We face significant competition in seeking strategic collaborations. Collaborations can also be complex and time-consuming arrangements to negotiate and document. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product or product candidate, reduce or delay one or more of our other development programs, delay or reduce the scope of any commercial readiness activities, delay commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. Our success in entering into a definitive agreement for any collaboration will depend upon, among other things, our assessment of the prospective collaborator's resources and expertise, the terms of the proposed collaboration and the proposed collaborator's evaluation of several factors. Those factors may include the design and outcomes of our clinical studies, the likelihood of approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such product to customers, the potential of competing products, the strength of the intellectual property and other potential sources of market exclusivity for such product, the market performance of other products we developed, and industry and market conditions generally. The prospective collaborator may also have opportunities to collaborate with third parties on products or technologies that would compete with our products or product candidates and will evaluate whether those opportunities are more attractive than a collaboration with us. We face competition in our search for collaborators from other biotechnology and pharmaceutical companies worldwide, many of which are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support. Inadequate capitalization of our company, or the perception thereof, could negatively affect our negotiating leverage in transactions.

We may also be restricted under existing collaboration agreements from entering into other collaborations on certain terms with other potential collaborators. For example, the terms of our exclusive license agreement also provide Organon exclusive worldwide rights of first negotiation for specified potential future products of ours, which may increase the complexity and time required, or otherwise inhibit our ability to transfer, license, sublicense, assign, grant or otherwise dispose of any rights in those potential future products to a third party, and lead to delays in their development and commercialization.

If we are not successful in attracting collaborators, entering into collaborations on acceptable terms and maintaining our collaborations for the products we develop, we may not complete development of or obtain regulatory approval for such products and product candidates, or if we obtain regulatory approval, commercial launch may be delayed and market penetration could be limited. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered which would materially harm our business and financial condition.

Prolonged failure to carry out its responsibilities or underperformance of NICHD under the CRADA, lack of additional federal government funding allocated to the CRADA budget, or termination of the CRADA, may significantly delay or jeopardize the conduct and completion of the ongoing Phase 3 clinical study of Ovaprene and significantly increase the overall development timeline and costs for Ovaprene.

The Phase 3 study of Ovaprene is being conducted, in part, under our CRADA with HHS, as represented by NICHD. As a result of the CRADA, the conduct and completion of the study is dependent, in part, on performance of NICHD and the third parties it engages to assist in the conduct of the study. Twenty clinical research sites from within the CCTN were initiated to enroll participants in the study. Currently, there are 15 active CCTN sites following enrolled participants in the study, but none are recruiting new participants. Enrollment is currently proceeding at five study sites outside of the CCTN that were initiated in 2025, funded by a grant we received in 2024 from the Foundation. Under the CRADA, NICHD, together with its selected CRO, is responsible for overseeing the clinical investigators in the conduct of the study at the CCTN sites, providing clinical site monitoring and quality assurance and performing data analysis, which are key factors to the successful completion of a clinical trial. We do not control those third parties and they may not perform as expected. For example, in 2024 there was slower than expected participant recruitment and enrollment at a number of the CCTN sites, leading to a decision by us and NICHD to proceed with recruitment at a subset of ten of the CCTN sites that had been initiated.

In the first quarter of 2025, executive orders and other actions taken by the new U.S. presidential administration have negatively impacted the Phase 3 study and NICHD's ability to carry out its responsibilities under the CRADA. In particular, the NICHD process to enter into contract modifications with the CCTN sites participating in the study in the same manner as it would ordinarily do to provide additional funding to those sites within the current budget under the CRADA has been impacted and remains uncertain. As a result, to help ensure CCTN sites remain active for continued follow-up with existing study participants, we and NICHD agreed to pause recruitment of new participants at all CCTN sites. Depending on its duration, this pause in recruitment at the CCTN sites could adversely impact the overall enrollment rate for the study and increase the time and cost to us to complete the study. In addition, most of the CCTN sites participating in the study are part of colleges or universities, and the federal government recently has terminated or threatened to terminate grants and contracts with colleges and universities, including clinical study contracts with at least one university that is a CCTN site in our study. Further, depending on the duration of the enrollment period and number of subjects enrolled in the Phase 3 study, there may be future costs associated with the study that are not reflected in the current budget under the CRADA for the CCTN sites. We and NICHD have been in discussions regarding the CRADA, which are continuing and which may include discussing a mechanism to potentially provide for additional future payments by us in support of the Phase 3 study for the CCTN sites to complete subjects already enrolled, in the event that the currently budgeted CRADA funds are insufficient. If NICHD is unable to enter into new contracts or contract modifications with CCTN sites for a prolonged period, or terminates its contracts with CCTN sites in our study before the study follow-up visits with existing participants are completed or before the study is completed, we may determine to contract directly with those sites to enable them to restart recruitment and enrollment of new participants and/or ensure they remain active sites to continue follow-up with existing participants, which could increase the time and cost to us to complete the study. In addition, if CCTN sites are closed, some participants may drop out of the study, which could adversely affect completion or results of the study.

Though the CRADA has a five-year term ending in 2026, either party may terminate it for any reason or for no reason upon 30 days' prior written notice to the other party. Termination of the CRADA by NICHD or by us could significantly delay the conduct and/or completion of the Phase 3 study and significantly increase the overall timeline and costs for development of Ovaprene. If the CRADA is terminated before completion of the Phase 3 study, NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study. If we terminate the CRADA before the completion of any active study protocol, we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the study. NICHD may retain and use the cash payments we have made under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination. Suspension by NICHD of activities under the CRADA or termination by NICHD or by us of the CRADA could have a material adverse effect on the Phase 3 study and on our business, results of operations and financial condition, and may cause the market price of our common stock to decline.

We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third-party suppliers and manufacturers for our clinical study supplies, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, fail to maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business.

We do not own or operate, and we currently have no plans to establish, facilities for manufacturing, storage and distribution, or testing of product candidates. We rely and expect to continue to rely on third parties to supply and manufacture our product candidates and other materials necessary to commence and complete pre-clinical testing, clinical trials and other activities required for regulatory approval of our product candidates, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials, and conducting stability testing. In addition, we expect to continue to rely on third parties for commercial production and supplies of any future products. This reliance on third-party manufacturers and suppliers subjects us to inherent uncertainties related to product safety, availability, quality and cost.

Our product candidates (including their component materials) must be manufactured, packaged, tested, and labeled in accordance with our specifications and in conformity with cGMP and other applicable regulatory requirements, which requires dedication of substantial resources to specialized personnel, facilities and equipment and sophisticated quality assurance, quality control, recordkeeping procedures. While our employees and consultants monitor and audit our CMOs' manufacturing processes and systems, we have limited control over our CMOs and they may fail to perform as expected. The facilities and quality systems of CMOs who produce our product candidates and their APIs must pass a pre-approval inspection for compliance with applicable regulations as a condition of FDA approval. Failure to pass inspections, or to timely remediate any compliance issues identified by the FDA, could substantially delay marketing approval. As long as we are the product candidate sponsor or the holder of the product approval or manufacturer of record with the FDA or other regulatory authority, we are ultimately responsible for

compliance with regulatory requirements for manufacturing and distribution of our product candidates and any future approved products, regardless of our lack of control over our third-party manufacturers and suppliers. Failure of those third parties to comply with cGMP and other applicable regulatory requirements may result in fines and civil penalties on us, suspension of production, delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval.

Our CMOs and component suppliers may experience delays in producing and supplying, or may become unable or unwilling to produce and supply, our clinical trial material or commercial supply material due to financial or personnel constraints, their obligations to, or their decision to prioritize the production and supply of products for, other customers, partial or full loss of their facilities, or supply chain disruptions, including as a result of geopolitical conflicts, macroeconomic events or conditions, natural or manmade disasters, or public health emergencies such as the COVID-19 pandemic. For example, our single source CMO for Ovaprene is located in an area of the U.S. that is vulnerable to tropical storms, hurricanes, flooding and tornadoes, which have potential to render its facilities inoperative for protracted periods. One or more of our CMOs may fail or be unable to perform at a time that is costly or inconvenient for us. We may not have adequate or any recourse against a CMO or supplier who does not perform or terminates its agreement with us if such non-performance or termination is excused under the applicable agreement.

We do not have long-term supply agreements with any of our CMOs or raw materials suppliers. We generally enter into manufacturing agreements on a project-by-project basis based on our development needs, which may heighten the risk of timely availability of sufficient quantities of our product candidates at acceptable costs for clinical trials. For example, we do not have any long-term manufacturing or supply agreements with the CMO from which we plan to obtain clinical supplies for our first Phase 3 clinical study of Sildenafil Cream or with the current supplier of the API for Sildenafil Cream. Future supplies of Sildenafil Cream or the raw materials required to produce it may be more difficult and costly to obtain because we do not have long-term supply contracts, which could make us more vulnerable to significant price increases. As we advance development of our product candidates, we will need to negotiate agreements for commercial supply and we may not be able to reach agreement on a timely basis or acceptable terms, or at all. In addition, the FDA or regulatory authorities outside of the U.S. may require that we have an alternate manufacturer of a product before approving it for marketing and sale in the U.S. or other jurisdiction, and securing such alternate manufacturer before approval of a marketing application could result in considerable additional time and cost prior to product approval.

Currently, we do not have alternative CMOs or API suppliers to back up our primary vendors of clinical trial material. Identification of and discussions with other vendors may be protracted and/or unsuccessful, or new vendors may not be successful in producing the same results as our current vendors on a timely basis at the appropriate volumes, at an acceptable cost, or at all. Therefore, if the current vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material or any future approved product for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results, and financial condition.

Any new CMO or API supplier would be required to qualify under applicable regulatory requirements. In some cases, the technical skills or technology required to manufacture our clinical trial material or commercial material may be unique or proprietary to the original CMO or supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such CMOs and suppliers or require us to obtain a license from them in order to have another third party manufacture our product candidates or any future approved product. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. In some cases, the FDA or a foreign regulatory authority may require us to conduct additional clinical or nonclinical studies, collect additional stability data, and provide additional information concerning any new CMO or supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. The process of identifying, verifying and transitioning to a new CMO or supplier could significantly delay development or regulatory approval of our product candidates or delay or disrupt commercialization of any approved product and substantially increase costs or result in significant loss of product sales and associated revenue.

If our CMOs encounter difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements, we may have insufficient quantities of material to support ongoing or planned clinical trials or to meet commercial demand for any approved product in the future. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical trials, increase the costs associated with our development programs, and depending upon the period of delay, require us to terminate the clinical trials completely and commence new clinical trials at significant

additional expense. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. Manufacturing or quality control problems may arise in connection with the manufacture of our clinical trial material or future approved product and CMOs may not be able to maintain the necessary governmental licenses and approvals to continue their manufacturing services for us.

In addition, with respect to any finished product or key components manufactured outside the U.S., such as the API for Sildenafil Cream, which is sourced from a supplier located in India, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, future currency fluctuations, increased shipping costs, or new or increased U.S. tariffs and trade disputes with other countries could increase our clinical development costs, and ultimately, our cost of goods sold, which could adversely impact our operating results and financial condition.

Any of the above factors could cause us to delay or suspend anticipated or ongoing clinical trials, regulatory submissions or commercialization of a product candidate, entail higher costs, or result in being unable to effectively commercialize an approved product. Our dependence on third parties for the manufacture of our product candidates or future approved products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Similarly, while Organon assumed manufacturing responsibility for XACIATO from us in December 2023, commercial production and supply of XACIATO remains subject to comparable manufacturing risks as described herein, and any interruption in the commercial supply of XACIATO that directly or indirectly results in significant loss of product sales could have a material adverse effect on future payments we may receive under the traditional royalty purchase agreement we entered into with XOMA.

In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties, increase the risk of manufacturing disruptions, and result in higher development costs or costs of goods sold.

Our agreement with ADVA-Tec restricts our ability to engage a manufacturing source for Ovaprene other than ADVA-Tec during Ovaprene's development period as well as following regulatory approval, subject to limited exceptions. If ADVA-Tec fails to provide sufficient clinical supply of Ovaprene on anticipated timelines, our ability to complete clinical development and seek regulatory approval of Ovaprene could be significantly delayed. A substantial scale up in production of Ovaprene clinical supplies was necessary to support the ongoing Phase 3 clinical study of Ovaprene, which took longer and was more expensive than anticipated, and if Ovaprene receives marketing approval, further substantial manufacturing scale up will be necessary. If Ovaprene receives marketing approval, failure by ADVA-Tec to provide sufficient commercial product quantities at reasonable costs could have a significant adverse effect on our revenue and ability to become profitable. Furthermore, for some key raw materials and components of Ovaprene, there currently is only a single source of supply, and alternate sources of supply may not be readily available.

We rely on, and intend to continue to rely on, third parties to conduct our clinical and nonclinical studies and execute other significant aspects of our product development programs. Failure of these third parties to successfully carry out their contractual duties, comply with our clinical protocols or regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our development timelines and/or failure of our programs.

Our business model relies on the outsourcing of important product development functions, tests and services to third parties. We rely on CROs, medical institutions, clinical investigators, laboratories, vendors and consultants to conduct all of our clinical trials and perform nonclinical testing. These third parties play a significant role in the conduct and timing of our clinical and nonclinical studies and the collection, management and analysis of study data, which are critical to our business. In addition, we have relied, and expect in the future to rely, on third parties to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals for our product candidates. We enter into agreements with these third parties governing their work for us, but we do not control them and have limited influence over their actual performance. They may not devote sufficient time and resources to our projects, or their performance may be substandard, resulting in clinical trial delays, suspensions or terminations, delays in submission of our marketing applications, failure of a regulatory authority to accept our applications for filing or receipt of a CRL. The performance of these third parties may also be negatively impacted by macroeconomic factors, geopolitical conflicts or events, natural or manmade disasters, public health emergencies, information system and cybersecurity incidents, and workforce challenges. In addition, these third parties may have relationships with companies developing competitive products and prioritize a competitor's clinical or nonclinical studies or regulatory affairs activities over their work for us, which could harm our competitive position. Because of our dependence on these third parties, if they fail to meet expected deadlines, adhere to our study protocols, meet regulatory and legal requirements, or otherwise perform in a substandard manner, we could suffer significant delays and additional costs in, and potentially failure of, the development of one or more of our product candidates.

Our CROs, study sites and other consultants generally have the right to terminate their agreements with us without cause upon the completion of a specified notice period, subject to limited restrictions. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner, or at all. Switching or adding additional CROs, study sites, and other third party service providers due to substandard or inadequate performance or termination of a relationship involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our communicated clinical development timelines. Though we work to carefully manage our relationships with our CROs, study sites, and other third parties, we have encountered challenges and delays in our clinical and nonclinical studies as a result of performance issues in the past, and there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

Our ability to develop and commercialize our product candidates depends upon maintaining rights granted to us under license agreements with third parties. The loss or impairment of our rights under our in-license agreements relating to XACIATO or our product candidates could have a material adverse effect on our business prospects, operations and viability.

We have rights to develop and commercialize XACIATO and our product candidates under license agreements between us and third-party licensors. The loss or impairment of these rights, including as a result of our inability or other failure (or that of our licensors, in the case of sublicenses) to meet our obligations under any one of such license agreements, including, without limitation, our payment obligations, could have a substantial negative effect on our business and prospects.

In December 2018, we entered into definitive agreements with Hammock Pharmaceuticals, Inc., TriLogic Pharma LLC and MilanaPharm LLC under which we acquired exclusive global rights to XACIATO for the treatment of bacterial vaginosis, as well as the rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological application in humans. Under the license agreement with TriLogic Pharma and MilanaPharm, we must use commercially reasonable efforts and resources consistent with those we undertake in pursuing development and commercialization of other pharmaceutical products, taking into account program-specific factors, (a) to develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany, Italy or Spain, and (b) following the first commercial sale of a licensed product or process in any jurisdiction, to continue to commercialize that product or process in that jurisdiction. In addition to customary termination rights, MilanaPharm may terminate our license with respect to a licensed product or process in a country if, after having launched such product or process in such country, we, or our affiliates or sublicensees, as applicable, discontinue the sale of, or commercially reasonable marketing efforts to sell, such product or process in such country, and fail to resume such efforts or to reasonably demonstrate a

strategic justification for the discontinuation and failure. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development-Hammock/MilanaPharm Assignment and License Agreement," above.

We entered into a license agreement with ADVA-Tec for the exclusive worldwide rights to develop and commercialize Ovaprene that became effective in July 2017. In addition to standard termination rights, ADVA-Tec may terminate the license agreement if we (1) fail to make significant scheduled investments in product development activities over the course of the agreement, (2) fail to commercialize Ovaprene within six months of obtaining a pre-market approval from the FDA, (3) with respect to the license in any particular country, fail to commercialize Ovaprene in that particular country within three years of the first commercial sale, (4) develop or commercialize a non-hormonal ring-based vaginal contraceptive device other than Ovaprene, (5) fail to conduct certain clinical trials, or (6) fail to make certain milestone, sublicense and/or royalty payments to ADVA-Tec. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development-ADVA-Tec License Agreement," above.

In February 2018, we entered into a world-wide license and collaboration agreement with SST for the exclusive worldwide rights to develop and commercialize Sildenafil Cream for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of FSAD. The SST license agreement provides that each party will have customary rights to terminate the agreement in the event of material uncured breach by the other party and under certain other circumstances. The SST license agreement provides SST with the right to terminate it with respect to the applicable SST licensed products in specified countries upon 30 days' notice if we fail to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan contained in the SST license agreement, or any updated development plan approved by the joint development committee, and do not cure such failure within 60 days of receipt of SST's notice thereof. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development-SST License and Collaboration Agreement," above.

In April 2018, we entered into the Catalent license agreement under which we acquired exclusive global rights to Catalent's IVR technology platform, including the product candidates we now call DARE-HRT1, DARE-FRT1, and DARE-PTB1. Under this agreement, we must use commercially reasonable efforts to develop and make at least one product or process available to the public, which efforts include achieving specific diligence requirements by dates specified in the agreement, and Catalent may terminate the agreement upon 60 days' notice for any uncured material breach by us of any of our other obligations under the agreement. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development-Catalent JNP License Agreement," above.

In May 2018, we completed our acquisition of Pear Tree and obtained exclusive global rights to certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration, which led to our DARE-VVA1 program. Under the applicable license agreements, as amended, we are required to use commercially reasonable efforts or reasonable best efforts to bring licensed products and processes to market, which include achieving specified milestones. The licensors may terminate the agreements for failure to make certain payments due to the licensors and any uncured material breach or default, including breach of our diligence obligations. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development—Pear Tree Acquisition and License Agreements," above.

In August 2023, we entered into a license agreement with Douglas for exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of CIN and other HPV-related pathologies, and commenced our DARE-HPV program. Under this agreement, we must use commercially reasonable efforts to develop and introduce to market at least one product or process, which efforts include achieving specific diligence requirements by dates specified in the agreement. Douglas may terminate the agreement for any uncured failure to make certain payments, any uncured material failure to fulfill our diligence obligations, or any other uncured material breach of our other obligations under the agreement. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development—Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement," above.

If we do not meet our obligations under our license agreements in a timely manner, some of which require the expenditure or payment to the licensor of significant amounts of cash, or if we are unable to obtain an extension of deadlines for satisfying our obligations, we could lose our rights under these agreements. Moreover, because some of our rights to XACIATO and our product candidates are sublicensed to us, our license agreements may be terminated or we may otherwise lose rights to intellectual property underlying our product or product candidates in the event of termination or loss of rights by our licensors, which may be outside of our control. There is no assurance that we would be able to renew or renegotiate license agreements on acceptable terms, or at all, if our existing license agreements (or the underlying agreements in the case of sublicenses) are terminated. Furthermore, we cannot guarantee that any license agreement will be enforceable. The termination of these license agreements or our inability to enforce our rights under these license agreements could result in the loss of our ability, or that of our sublicensees,

to develop, manufacture, market or sell XACIATO or the product candidate covered by the agreement, as well as our ability to grant rights to other third parties to collaborate with us in the development and commercialization of our product candidates and our ability to receive milestone and royalty payments from third-party sublicensees, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the timing and amount of milestone or royalty payments due to the licensor;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize, or maintain third-party collaborations to commercialize, the affected product or product candidate.

We may seek to license the product and technology rights to additional product candidates in accordance with our business strategy, but there can be no assurance we will be able to do so on favorable terms or at all. There are risks, uncertainties and costs associated with identifying, licensing and advancing product candidates through successful clinical development. Even if we obtained the rights to additional product candidates, there can be no assurance those candidates would ever be advanced successfully through clinical development.

Risks Related to Commercialization of Products We Develop

We have no internal sales, marketing or distribution capabilities, and we may need to invest significant resources to establish those capabilities. If we are unable to timely establish those capabilities on our own or through arrangements with third parties, product launch may be delayed, commercialization may be adversely impacted, and we may not be able to generate product sales revenue.

We currently do not have, and have never had, product marketing, sales or distribution infrastructure. In order to commercialize any of our product candidates, if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. As we move our product candidates through development toward, and in some cases, through regulatory approval, we evaluate several options for each product candidate's commercialization strategy. These options include building our own sales force and other commercial infrastructure, or collaborating with third parties that have established sales forces and distribution systems, either to augment our own sales force and commercial infrastructure or in lieu of establishing our own sales force and commercial infrastructure. We currently have no commercialization agreements with third parties other than our license agreements with Organon for XACIATO and Bayer for Ovaprene. We may not be able to maintain our existing commercial collaborations or establish and maintain other commercial collaborations on favorable terms, on a timely basis, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties to commercialize products we develop than if we were to do it ourselves.

To generate revenue from our product candidates, if approved for commercial sale, we may need to establish our own sales forces and commercial infrastructure. There are significant challenges and risks involved with building and managing a sales organization and other commercial infrastructure, even if we collaborate with third parties that have established sales forces and distribution systems to augment our own capabilities, including:

- difficulties in recruiting and retaining adequate numbers of qualified individuals;

- providing adequate training for sales and marketing and support personnel;
- effectively managing a geographically dispersed sales force;
- difficulties generating sales leads;
- potential lack of complementary products our sales personnel may be able to offer compared with sales personnel for competitive products; and
- unforeseen costs and expenses associated with establishing a new corporate function and the rapid growth of our company.

Recruiting, incentivizing and training a sales force is expensive and requires substantial management time and focus. If we recruit and train a sales force and the commercial launch of the product is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred significant expenses, and our investment would be lost if we could not retain or reposition our sales and marketing personnel. On the other hand, if we do not timely establish a sales force and other commercial infrastructure, a product launch may be significantly delayed, adversely impacting the potential commercial success of the product, as well as our operating results and financial condition. Both the launch and ongoing commercial support of our products would require significant capital, which may not be available to us when needed or on acceptable terms or at all. All of these factors could strain our cash resources and require us to raise additional capital.

Failure or delay in entering into and maintaining arrangements with third parties to market and sell, or assist us in marketing and selling, our product candidates, if approved for commercial sale, or in establishing capabilities to independently commercialize our product candidates could significantly delay commercial launch and negatively impact their potential commercial success, which could have a material adverse effect on our business, financial condition and results of operations.

Our product candidates, if approved for commercial sale, will face intense competition and our business and operating results will suffer if we, or our commercial collaborators, fail to compete effectively.

The pharmaceutical industry is intensely competitive and characterized by rapid technological developments. Moreover, the women's health sector is very fragmented and highly competitive. We anticipate that our product candidates may compete not only with FDA-approved, prescription and over-the-counter, branded and generic drug products, but also compounded drugs, medical devices, dietary supplements, and cosmetics. We face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies and specialty pharmaceutical companies that already possess robust product portfolios and strong franchises in women's health in areas in which we plan to compete, as well as generics manufacturers, compounding pharmacies and other drug compounding facilities, and dietary supplements manufacturers. In addition, academic and other research institutions are and could be engaged in research and development efforts for products in the therapeutic areas targeted by our product candidates. Many of our competitors or potential competitors, either alone or with strategic collaborators, have:

- much greater financial, research, technical and human resources than we have at every stage of the product development and commercialization life cycle;
- more extensive experience in designing and conducting clinical trials, nonclinical studies, obtaining regulatory approvals, and in manufacturing, marketing and selling prescription medical products; and
- approved products or product candidates in late stages of development for one or more of our target indications.

Competitive products may be equally safe and as effective as our products, but sold at a substantially lower price. Alternatively, competitive products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than our products.

Many of our product candidates, if approved for commercial sale, will compete with products that have already been accepted by the medical community and patients. If our product candidates fail to generate compelling clinical results or if patients and health care providers fail to adopt our products for their respective indications, their commercial potential could be adversely impacted or severely diminished. It is possible that the potential advantages of our product candidates do not materialize or that the approved prescribing information for our products does not describe expected features or benefits. We also expect to face competition from new products that enter the market over time. We are aware of products currently under development intended for the same indications as our product candidates. These competitive product candidates may prove safer, more tolerable, more effective, and less expensive, and may be introduced to market earlier, or produced, marketed and sold more effectively or on a more

cost-effective basis, than our product candidates. The success of competitive products may render our product candidates noncompetitive or obsolete, even prior to completion of their development.

With respect to XACIATO, there are multiple generic and branded prescription drug products currently approved in the U.S. for the treatment of bacterial vaginosis, including oral and vaginal gel formulations of metronidazole and vaginal cream formulations of clindamycin. If health care providers do not view the prescribing information for XACIATO as compelling compared with other products available for the treatment of bacterial vaginosis, or if competitive products have better insurance coverage or reimbursement levels than XACIATO, health care providers may opt to prescribe a competitive product rather than recommend or prescribe XACIATO to their patients. In addition, women may prefer orally delivered options to vaginally administered XACIATO unless they view XACIATO as providing significantly superior efficacy, safety and/or convenience. If our commercial collaborator fails to generate significant net sales of XACIATO which exceed the Revenue Sharing Threshold, we will not have any future revenue stream relating to XACIATO.

The women's health market includes many generic FDA-approved drug products, compounded drugs, as well as dietary supplements and consumer health products, and growth in these categories is expected to continue, which could make the successful introduction of our products difficult and expensive.

The proportion of the U.S. drug market made up of generic products has been increasing. In addition, compounded drugs and dietary supplements in women's health are multi-billion dollar markets. As a result, even if our product candidates are approved, it may be more difficult for us or a commercial collaborator to introduce a new product, particularly a branded prescription product, at a price that will allow us to achieve acceptable levels of revenue and net income from product sales. Generic competition is particularly strong in contraception and hormone therapy, which are areas in which we seek to compete. Our product candidates for menopause symptoms will additionally have to compete with compounded hormones supplied by compounding pharmacies and other drug compounding facilities, as well as dietary supplements marketed for relief of menopause symptoms. Compounded sildenafil cream medications are also currently being supplied by compounding pharmacies and other drug compounding facilities. In order for our branded products to develop commercial markets and for third-party payors to cover these higher cost products, our products must demonstrate better patient compliance and clinical benefit as compared to what other available products have demonstrated.

Additional marketing and educational efforts may be required to introduce a new branded prescription medical product in order to overcome use of generic products, compounded drugs and dietary supplements and gain access to reimbursement by payors. If we or a commercial collaborator cannot introduce a product at the desired price or gain reimbursement from payors for the product, or if patients opt for a lower cost generic product, compounded drug, or dietary supplement rather than pay out-of-pocket or a higher co-pay for our product, our sales revenues or royalties and other license fees, as applicable, will be limited and we may never become profitable.

Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, which would negatively impact our business.

The commercial success of any product we develop and bring to market, or is marketed by a licensee, will depend significantly on the broad acceptance of the product by physicians, patients, and others in the medical community, as well as, in many cases, third-party payors. The degree of market acceptance of our products will depend on several factors, including:

- the indication for which the product is approved;
- the timing of market introduction of the product and availability of alternative treatments and products for the same indication;
- the demonstrated clinical efficacy and safety of the product, including as compared to alternative products;
- the terms of regulatory approval, such as any restrictions on the use of the product together with other medications, or required warnings in the product labeling;
- the prevalence and severity of any adverse side effects associated with the product, including as compared to alternative treatments and products;
- the convenience and ease of administration for patients, including as compared to alternative treatments and products;
- the willingness of the target patient population and prescribing physicians to try a new product ;

- the effectiveness of the sales and marketing strategy and efforts for the product, including the success of efforts to educate the medical community and third-party payors regarding the benefits of the product;
- the pricing and cost-effectiveness of the product, including as compared to alternative treatments and products;
- the availability and extent of third-party coverage and reimbursement for the product;
- the willingness of patients to pay all, or a portion of, the out-of-pocket cost for the product in the absence or insufficiency of third-party payor coverage and reimbursement;
- unfavorable publicity relating to the product or products with the same or similar APIs, or favorable publicity about competing therapies or products; and
- the existence and extent of pending or potential product liability claims.

If XACIATO or any future product does not achieve an adequate level of market acceptance, the product may not generate significant revenue or may generate substantially less revenue than anticipated, which could have a material and adverse effect on our business, financial condition, results of operation and prospects. We may suffer reputational harm and we may never become profitable.

The commercial success of XACIATO is outside of our control and will depend on Organon's efforts and capabilities, as well as a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our business and prospects may suffer.

If commercialization of XACIATO is not successful, or is perceived to be unsuccessful, our business, financial condition, results of operations and prospects may suffer, particularly because XACIATO is the first and only product for which we have received regulatory approval. XACIATO's commercial success will depend on many factors, including those discussed elsewhere in these "Risks Related to Commercialization of Products We Develop" and "Risks Related to Our Intellectual Property" below, as well as the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product, preferences by health care providers and women for a vaginally administered therapy, and regulatory approval and market introduction of alternative therapies, including non-antibiotic treatment options. We have limited control over Organon's efforts with respect to XACIATO and there is no assurance they will be successful or that the Revenue Sharing Threshold will be reached. As discussed elsewhere in this Risk Factors section, we will not receive any payments based on product sales until after the Revenue Sharing Threshold is reached. We may suffer reputational harm if XACIATO is not commercially successful and our ability to raise additional capital or enter into other commercial collaborations could be impaired. See also the risks and uncertainties described under "Risks Related to Our Dependence on Third Parties," above.

The commercial success of Ovaprene, if approved for commercial sale, will depend on the degree of market acceptance of a hormone-free, monthly intravaginal product, clinical efficacy and safety of the product, including as compared to alternative contraceptive methods, pricing of the product, and the availability and extent of third-party coverage and reimbursement for the product, as well as other factors including Bayer's marketing and sales efforts.

Today, there is a wide range of prescription and over-the-counter contraceptive options, including hormone-free options such as condoms, diaphragms, cervical caps, sponges, copper IUDs, spermicides and vaginal gels, as well as hormonal products such as pills, patches, vaginal rings, IUDs, implantable rods and injectables. In addition, multiple new methods of pregnancy prevention are in development, including hormone-free options, and some may be marketed in the U.S. before Ovaprene, potentially adding to the level of market competition Ovaprene will face, if approved. In surveys, women have said that the features they consider most important when selecting a contraceptive method are efficacy, ease-of-use and side effects. To have significant revenue potential as a new contraceptive product option, Ovaprene may need to demonstrate typical use efficacy (or the expected rate of pregnancy protection once the product is used widely under everyday circumstances) that approaches the approximately 93% typical use efficacy at 12 months of current FDA-approved non-implanted, non-injected hormonal contraceptive methods (pills, patches and vaginal rings). Clinical testing will also need to demonstrate that the product can be safely worn for multiple weeks.

If Ovaprene receives regulatory approval, its commercial success, or the success of any other future contraceptive product we develop, including our current early clinical-stage and pre-clinical stage candidates, will depend upon the contraceptive market and market acceptance of an alternative method. Factors expected to impact broad market acceptance of a new contraceptive product include those discussed above under "Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors or others

in the medical community necessary for commercial success, which would negatively impact our business," as well as:

- demonstration of minimum acceptable contraceptive efficacy rates;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options;
- competition from new lower dose hormonal contraceptives with more favorable side effect profiles compared with higher dose hormonal contraceptives;
- preference for a monthly format product over contraceptive products to be taken daily or used in the moment;
- preference for an intravaginal product over other formats such as pills, patches, injectables and condoms;
- generic contraceptive options, including generic versions of the hormone-containing intravaginal product NuvaRing®; and
- the effects of changes in health care laws and regulations on third-party payor coverage (including the birth control coverage mandate) and reimbursement and out-of-pocket costs to patients.

If one or more of these risks occur, it could reduce the market potential for Ovaprene, or any other contraceptive product we develop, and place pressure on our business, financial condition, results of operations and prospects.

Under our license agreement with Bayer, provided the license grant becomes effective, Bayer will have exclusive rights to market and sell Ovaprene in the U.S. Accordingly, the potential value of Ovaprene to our company may be highly dependent on the efforts and activities of Bayer. Should Ovaprene fail to generate compelling clinical safety and efficacy data, the license grant under our agreement with Bayer may never become effective. Even if Bayer elects to make the license agreement effective, Bayer has significant discretion in determining the resources that it will allocate to commercialization of Ovaprene and Ovaprene's commercial success may be limited, in which case our business, financial condition, results of operations and prospects could suffer significantly.

The commercial success of an FDA-approved Sildenafil Cream product will depend on the availability of alternative treatments and products, the effectiveness of the sales and marketing strategy and efforts for the product, including the success of efforts to educate women and their health care providers about FSAD, and the availability and extent of third-party coverage and reimbursement for the product, among other factors.

Today, there are no FDA-approved products to treat FSAD. While our goal is for Sildenafil Cream to be the first product to receive such approval, one or more competitive products may be approved before our product. In addition, an FDA-approved Sildenafil Cream product may also have to compete with compounded drugs. Some compounding entities currently supply topical cream formulations of sildenafil. In addition, some compounding entities have partnered with telemedicine providers, enabling them to expand the potential market for their compounded drugs. The availability of cream formulations of sildenafil through compounding entities, could make it more challenging for Sildenafil Cream to build and maintain market share. Even if we achieve our goal of being first-to-market for FSAD, the costs associated with introducing a new branded prescription product into the female sexual dysfunction market would likely be significant, and regardless of the amount spent, there is no guarantee that our new product will be broadly adopted. Broad market adoption of Sildenafil Cream will depend not only on Sildenafil Cream's ability to demonstrate safety and effectiveness in treating FSAD in Phase 3 clinical trials, but a variety of factors, as discussed above under "Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, which would negatively impact our business." If we or a commercial collaborator are not successful in increasing awareness and understanding about FSAD and Sildenafil Cream, the market potential of Sildenafil Cream will not be realized. Women who experience low or no genital arousal may be hesitant to seek treatment due to stigma and embarrassment associated with sexual health issues, lack of understanding of normal versus abnormal sexual functioning, or lack of awareness that FSAD may be treated with medication. Health care providers may be hesitant to prescribe Sildenafil Cream for many reasons, including lack of understanding or experience with female sexual dysfunction in general and FSAD in particular, lack of experience with any product approved to treat FSAD, or perceived lack of clinical evidence of the safety and efficacy of Sildenafil Cream. Women may also be hesitant to use Sildenafil Cream for many reasons, including the lack of experience with any product designed to treat FSAD, concern over potential side effects, and the out-of-pocket cost of Sildenafil Cream, particularly if it is not covered by insurance. Currently, third-party payors such as government health care programs and private insurance companies often do not cover products prescribed to treat female sexual dysfunction disorders. If Sildenafil Cream is not an affordable option for a significant segment of potential users, the ability to build a commercial market for Sildenafil Cream will be significantly impaired.

In addition, FSAD is a condition that impacts women of many ages, including older and elderly populations. We have not yet thoroughly studied the topical or clinical pharmacology of Sildenafil Cream in different patient

populations, and sildenafil, the active ingredient in our drug candidate, has not been tested over long periods of time in older or elderly women. Older or elderly women may react differently and adversely to Sildenafil Cream than younger populations. We expect our pivotal Phase 3 clinical trials of Sildenafil Cream will be conducted in a premenopausal population. Therefore, we expect initial FDA approval of Sildenafil Cream, if received, to be limited to premenopausal women. Should Sildenafil Cream not be studied in older or elderly women, or, if studied in those populations, should it show increased risk of adverse reactions, or signs thereof, in older or elderly women during clinical development, the potential market for Sildenafil Cream could be significantly limited, which could have a material adverse impact on the value of this program.

The commercial success of DARE-HRT1, if approved for commercial sale, will depend on the availability of alternative products for managing menopause symptoms, concerns about the safety of hormone therapy, and women's preferences, among other factors.

DARE-HRT1, if approved as a treatment for moderate to severe VMS due to menopause, will compete with the many options on the market targeted to or FDA-approved for the treatment of menopausal symptoms, including VMS. Such options include hormone therapies in the form of pills, patches and creams, some of which are FDA-approved products and others which are supplied by compounding entities, as well as non-hormonal options, including an FDA-approved product (Veozah® (fezolinetant)), and dietary supplements. Both the supplement and the compounded hormone therapy markets are very significant. A considerable segment of the compounded hormone therapy market is comprised of compounded hormones in pellet form that are implanted under the skin as a non-daily alternative, which could be directly competitive with DARE-HRT. In addition, we are aware of non-hormonal drug products in development for the treatment of VMS, including elinzanetant, a dual neurokinin-1 and 3 (NK-1 and NK-3) receptor antagonist, for which Bayer submitted an NDA in August 2024, and is anticipated to launch in the second half of 2025. We expect the options for hormone therapy to continue to expand with time. DARE-HRT1 is designed to offer a convenient vaginal ring that continuously delivers a combination of bioidentical estradiol and progesterone over 28 days. Bioidentical hormones refer to compounds that are chemically identical to those produced naturally in the human body. Studies have not demonstrated that bioidentical hormones are safer than synthetic hormones, so DARE-HRT1 will need to compete with many types of hormone therapy options in terms of convenience, safety and efficacy in managing symptoms of menopause.

Risks related to market acceptance of DARE-HRT1 include:

- women's preference for vaginal ring delivery of hormone therapy over pills, patches and creams;
- women's preference for a monthly product format over products to be taken or applied daily;
- data regarding symptom relief of DARE-HRT1 compared with other treatments and products for VMS;
- preference for bioidentical hormones by women and health care providers;
- positive or negative news and research regarding hormone therapy in general and bioidentical hormone therapy in particular;
- preference for an FDA-approved product by women and health care providers over treatments prepared in compounding entities;
- the success or failure of other FDA-approved bioidentical hormone products and FDA-approved non-hormonal products for VMS;
- new information supportive or against the use of hormones in menopause; and
- availability and extent of third-party payor coverage and reimbursement for DARE-HRT1 and out-of-pocket cost for patients.

Depending upon the direction of the factors above, a commercial market for DARE-HRT1 may develop more slowly than expected, or not at all, and our business, financial condition, results of operation and prospects could be hurt as a result.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses for prescription medical products. If we or any commercial collaborator is found or alleged to have improperly promoted any of our products for off-label uses, we may become subject to significant liability, including fines, penalties or injunctions, and reputational harm.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription medical products. In particular, a product may not be promoted for uses that are not approved by the FDA (i.e., off-label uses), as reflected in the product’s approved or cleared labeling. Promotional labeling and advertising for any of our drug product candidates that receive marketing approval, must be submitted to FDA at the time of first use and the agency actively solicits reports from health care professionals about improper promotional claims or

activities by the drug manufacturer or distributor. Medical device promotion and advertising are subject to similar off-label restrictions, although without the same requirement to submit promotional materials to FDA at the time of first use. Both prescription drug and medical device promotional materials must present a fair balance between the product's effectiveness and the risks associated with its use, and must be truthful and not misleading.

If we or a commercial collaborator is alleged or found to have promoted a product for any off-label use, we may become subject to significant liability and reputational harm. The federal government has levied large civil and criminal fines against companies for alleged improper medical product promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Other enforcement authorities may also take action against a company for promoting an off-label use of a prescription medical product, which could result in penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. See also "Risks Related to Our Business Operations and Industry- The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act" below.

If we or our commercial collaborators, as applicable, cannot successfully manage the product promotion to ensure compliance with these legal and regulatory requirements, we could become subject to significant liability, our reputation could be damaged, and adoption of our products could be considerably impaired.

Unexpected safety, efficacy or quality concerns relating to XACIATO could develop, which could have significant negative consequences for us.

XACIATO was approved by the FDA based on prior findings of safety or effectiveness of previously approved clindamycin products and on clinical data from the Phase 3 DARE-BVFREE clinical trial, in which 307 patients were randomized and treated once. In light of its commercial launch, XACIATO will be used by larger numbers of patients, and some patients may use multiple regimens over the course of a year. New data may emerge from market surveillance or future clinical trials of XACIATO that give rise to safety, efficacy or quality concerns and result in negative consequences, including:

- modification to the product's prescribing information, such as the addition of boxed or other warnings, contraindications, or limitations of use;
- restrictions on the promotion or marketing of the product;
- issuance of "Dear Doctor Letters" or similar communications to health care professionals or the public regarding safety or efficacy concerns;
- imposition of post-marketing clinical trial requirements or other post-marketing studies;
- product distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy, or REMS, which could include elements to assure safe use;
- warning or untitled letters;
- suspension or withdrawal of marketing approvals;
- suspension or termination of ongoing clinical trials, if any;
- refusal by regulators to approve pending marketing applications or supplements to approved applications that we submit;
- suspension of, or imposition of restrictions on, the operations of our commercial collaborator or any CMO producing commercial supplies of XACIATO, including costly new manufacturing requirements;
- costly and time-consuming corrective actions;
- voluntary or mandatory product recalls or withdrawals from the market;
- significant reputational harm; and
- product liability claims and lawsuits.

Furthermore, the discovery of significant problems with another intravaginally administered or clindamycin-containing product perceived as comparable to XACIATO, could have an adverse impact on commercialization of XACIATO, including as a result of occurrence of the events described above. For example, XACIATO has not been studied in pregnant or breastfeeding women. Should increased risk of miscarriage or other adverse effects on maternal or fetal outcomes or breastfed infants be observed in future data from market surveillance or clinical trials of XACIATO or other clindamycin products, XACIATO's commercial potential may be limited and we could become subject to product liability claims and lawsuits.

The occurrence of any of the circumstances described above could reduce XACIATO's market acceptance and adversely affect sales of XACIATO in the U.S. and inhibit or delay its development, approval or commercialization outside of the U.S., which could, in turn, have a significant negative impact on potential payments to us under the traditional royalty purchase agreement we entered into with XOMA, as well as our stock price.

If we suffer negative publicity concerning the safety or efficacy of XACIATO or the product candidates we develop, our reputation could be harmed, product sales could be adversely affected or we may be forced to cease or curtail product development efforts.

If concerns should arise about the actual or anticipated clinical outcomes regarding the safety of any of our product candidates, or about adverse event reports on XACIATO, including as a result of safety concerns related to third-party products containing the same or similar active or excipient substances, such concerns could adversely affect the market's perception of XACIATO and our product candidates. Negative publicity could be time consuming and expensive to address and could adversely affect potential opportunities with strategic partners or collaborators, lead to a decline in product sales, and negatively impact investor sentiment toward a product or product candidate or our company as a whole, which could lead to a decline in our stock price.

We are and will remain subject to ongoing regulatory requirements even after obtaining regulatory approval for a product candidate.

Even if any of the product candidates we develop are approved by the FDA or a comparable regulatory authority outside of the U.S., as long as we are the holder of the product approval or manufacturer of record with the FDA or other regulatory authority, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities.

In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in our NDA or PMA submissions to the FDA.

Any marketing approvals we receive for our product candidates in the future may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. In addition, we will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities (when products are approved in foreign markets). Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance.

If a regulatory agency discovers previously unknown problems with a product, such as problems with the facility where the product is manufactured, or it disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or on us or our commercial collaborator, including requiring withdrawal of the product from the market. If we or our commercial collaborators are unable to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would require us and/or our commercial collaborators to expend significant time and resources in response and could generate adverse publicity. Any inability to comply with ongoing regulatory requirements may significantly and adversely affect our ability, or that of our collaborators, to develop and commercialize our products and the value of our business, and our operating results would be adversely affected.

Failure to successfully obtain coverage and reimbursement for XACIATO and any future products in the United States, or the availability of coverage only at limited levels, would diminish our ability, or that of a commercial collaborator, to generate net product revenue or net sales.

Coverage from government health care programs and private commercial health insurance companies is critical to the commercial success of XACIATO and any future products. Market acceptance and sales of XACIATO and any future products that we or a commercial collaborator may seek to commercialize will depend in part on the extent to which reimbursement for these products will be available from third-party payors. Third-party payors, such as government health care programs, private health insurers, managed health care providers, and other organizations, are increasingly challenging medical product prices and examining the medical necessity and cost-effectiveness of medical products, in addition to their safety and efficacy. If these third-party payors do not consider XACIATO or any future product to be medically necessary or cost-effective compared to other available therapies and medical products, they may not cover the product as a benefit under their plans or, even if they do, the level of payment may not be sufficient to allow us, or a commercial collaborator, to sell the product on a profitable basis. Coverage decisions can depend upon clinical and economic standards that disfavor new prescription medical products when more established or lower cost alternatives are already available or subsequently become available. Third-party payor coverage may not be available to patients for XACIATO or any future product. If third-party payors do not provide adequate coverage and reimbursement, health care providers may not prescribe our products or patients may ask their health care providers to prescribe competing products with more favorable reimbursement.

Significant uncertainty exists as to the reimbursement status for newly approved prescription medical products, including coverage and payment. There is no uniform policy requirement for coverage and reimbursement for prescription medical products among third-party payors in the U.S.; therefore, coverage and reimbursement for our products could differ significantly from payor to payor. In the U.S., the principal decisions about reimbursement for new medical products are typically made by the Centers for Medicare and Medicaid Services, or CMS, as CMS decides whether and to what extent a new medical product will be covered and reimbursed under Medicare. Third-party payors often rely upon Medicare coverage policy and payment limitations to a substantial degree in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. It is difficult to predict what CMS will decide with respect to reimbursement. Decisions regarding the extent of coverage and amount of reimbursement to be provided for XACIATO and any future products will be made on a payor-by-payor basis. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Moreover, reimbursement agencies in Europe may be more conservative than CMS, should XACIATO or any of our product candidates be approved for marketing in Europe.

In addition to CMS and private payors, professional organizations can influence decisions about reimbursement for new medical products by determining standards of care. In addition, many private payors contract with commercial vendors who sell software that provides guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit as compared to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of any of our commercialized products.

To secure coverage and reimbursement for XACIATO and any future product, we or a commercial collaborator may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product to third-party payors, which costs would be in addition to those required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Third-party payors increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for XACIATO or any future product, or obtaining such pricing or placement at unfavorable pricing levels, could materially adversely affect our business, financial conditions, results of operations and prospects. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, or those of a commercial collaborator. Interim payments for new products, if applicable, also may not be sufficient to cover our costs, or those of a commercial collaborator, and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S.

Accordingly, the coverage determination process is often a time-consuming and costly process that will require us or our commercial collaborator to provide scientific and clinical support for the use of our products to each

payor separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payor will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be cost prohibitive for health care providers or their patients, or less profitable than alternative treatments or products, or if administrative burdens make our products less desirable to use. Our inability, or that of our commercial collaborator, to obtain coverage and profitable payment rates from both government-funded and private payors for XACIATO or any future product could have a material adverse effect on our operating results, our ability to raise capital needed to execute our business strategy and our overall financial condition.

Failure by us or a commercial collaborator to obtain timely and adequate coverage and pricing for a product, or obtaining such coverage and pricing at unfavorable levels, could materially adversely affect our business, financial condition, results of operations and prospects.

Legislation and legislative and regulatory proposals intended to contain health care costs may adversely affect our business.

The containment of health care costs has become a priority of federal and state governments and the prices of drug products have been a focus of this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that federal, state and local governments in the U.S. will continue to consider legislation directed at lowering the total cost of health care and prescription drugs. Individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

The Biden Administration has also indicated that lowering prescription drug prices is a priority, and on August 16, 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, the Centers for Medicare and Medicaid Services, or CMS, will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the U.S. remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing. Further, in December 2023, the Biden Administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"), and the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

It is uncertain whether and how future legislation or regulatory changes could affect prospects for XACIATO or our product candidates or what actions third-party payors may take in response to any such health care reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms, may prevent or limit our ability, or the ability of a commercial collaborator, to commercialize any future products as well as our ability to generate revenue and attain profitability.

Even seemingly small copayments or other cost-sharing requirements could dramatically reduce the market potential for XACIATO and our product candidates.

If the out-of-pocket costs for XACIATO or any of our product candidates, if approved for commercial sale, are deemed by women to be unaffordable, or if less expensive alternatives exist, a commercial market may never develop or the market potential for that product may be significantly reduced, which could have a material adverse effect on our business, financial condition, and prospects.

With regard to contraceptive products, the ACA and subsequent regulations enacted by DHHS, require health plans to provide coverage for women's preventive care, including all forms of FDA-cleared or approved contraception, without imposing any cost sharing on the plan beneficiary. These regulations ensure that women in the U.S. who wish to use an approved form of contraception may request it from their doctors and their health insurance plan must cover all costs associated with such contraceptive products. In January and July of 2022, the DHHS, Department of Labor, and Treasury Department jointly issued guidance on implementation of this ACA mandate, among other things. The federal guidance makes clear that all FDA-approved or cleared contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without cost sharing, regardless of whether the product is specifically identified in a Birth Control Guide published by the FDA. Any future repeal or elimination of the ACA's preventive care coverage rules would mean that women seeking to use prescribed forms of contraceptives may have to pay some portion of the cost for such products out-of-pocket, which could deter some women from using prescription contraceptive products or branded prescription contraceptive products, including Ovaprene and our other investigational contraceptive products, if and when approved by the FDA.

As no FDA-approved treatments for FSAD currently exist, there is little precedent to help assess whether health insurance plans will cover Sildenafil Cream, if approved for commercial sale.

Sildenafil Cream is being developed for female sexual arousal disorder, a life altering, but not a life threatening, condition. Hence, there is no assurance that third-party reimbursement will be available for Sildenafil Cream, if approved for commercial sale. Even if reimbursement becomes available, the amount of such reimbursement may not make our product affordable to women and profitable to us. Insurers may deem Sildenafil Cream to be a lifestyle drug and decide not to provide reimbursement. Today, many health insurance plans provide reimbursement for male sexual arousal medications. However, we cannot predict whether they will continue to do so or whether they will do so for FSAD treatments as well. The safety and efficacy data from our clinical trials may impact whether Sildenafil Cream will become eligible for insurance coverage, and if it does, the level of such reimbursement. In an environment of rapidly rising health care costs, insurers have been looking for ways to reduce costs, which could make it difficult for new therapies to gain coverage if they are not deemed medically critical or essential. If Sildenafil Cream fails to obtain insurance coverage, or if the patient's share of the cost is deemed to be expensive, a market may never develop for Sildenafil Cream, which would have a material adverse effect on our financial condition and prospects.

The commercial success of products we develop, if approved for commercial sale, will be impacted by the prescribing information approved by the FDA and comparable regulatory authorities outside the U.S.

The commercial success of any products we develop will significantly depend upon our ability, or that of our commercial collaborator, to obtain approval from the FDA and other regulatory authorities of prescribing information for the product that adequately describes expected features or benefits. Failure to achieve such approval will prevent or substantially limit our or our collaborators' ability to advertise and promote such features and benefits in order to differentiate our products from competing products. This failure could have a material adverse effect on our business, financial condition, results of operations and prospects.

Manufacturing disruptions could cause significant delays and disruption in the commercial launch and/or supply shortages of any product we develop.

The manufacture of drug products and drug/device combination products can be complex and is subject to compliance with extensive regulatory requirements and we are dependent on, and expect to continue to rely on, contract manufacturers and other third parties to supply our products and their components. Manufacturing disruptions may occur, including as a result of scaling up production to meet commercial requirements or due to global supply chain disruptions. Such problems may prevent the production of lots that meet the specifications required for sale of a product and may be difficult and expensive to resolve. To the extent we or our commercial collaborators rely on single source contract manufacturers and suppliers, if disruptions occur in the operations of any one of those third parties, there may be immediate shortages of our products. If any such issues were to arise, we could lose sales and associated revenue, incur additional costs, delay commercial launch of new products or suffer harm to our reputation.

See above: “Risks Related to Product Research & Development and Regulatory Approval- Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products.”; “Risks Related to Our Dependence on Third Parties- We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third-party suppliers and manufacturers for clinical study materials, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, do not maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business;” and “Risks Related to Our Dependence on Third Parties- In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties, increase the risk of manufacturing disruptions, and result in higher development costs or costs of goods sold.”

If competitors obtain approval for generic versions of our products, our business may suffer.

XACIATO and any future product we develop may face direct competition from generic products earlier or more aggressively than anticipated, depending upon the product's success in the market. In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Act amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications, or ANDAs. An ANDA relies on the nonclinical and clinical testing conducted for a previously approved reference listed drug, or RLD, and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is “bioequivalent” to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If a third party is able to demonstrate bioequivalence without infringing our patents or if a data exclusivity period granted to a product under the FDCA is successfully challenged, a third party may be able to introduce a competing generic product onto the market before the expiration of the applicable patents or exclusivity period under the FDCA. Reduction or loss of periods of market exclusivity for our products could negatively affect our business, operating results and financial condition.

We will need to obtain FDA approval of any proposed prescription medical product name, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our current or future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed new prescription medical product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a proposed product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose any goodwill or brand recognition developed for previously used names and marks, such as Ovaprene, as well as the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. We or a commercial collaborator may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our or our collaborator’s ability to commercialize our product candidates.

Even if we receive marketing approval from the FDA, we may fail to receive similar approvals outside the U.S., which could substantially limit the value of our products.

To market any product outside the U.S., we, or our commercial collaborators, must obtain separate marketing approvals from comparable regulatory authorities for each jurisdiction and comply with numerous and varying regulatory requirements of other countries, including clinical trials, commercial sales, pricing, manufacturing, distribution and safety requirements. The time required to obtain approval in other countries might differ from, and be longer than, that required to obtain FDA approval. Approval by the FDA or a comparable foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the U.S., as well as other risks. Further, for approval in foreign jurisdictions, we may not have rights to reference the necessary clinical and nonclinical data that we do not own or have licensed rights to use, as we anticipate doing under the 505(b)(2) regulatory pathway in the U.S., and we, or our commercial collaborator, may have to conduct further

nonclinical studies or clinical trials or develop other additional data to seek approvals in other jurisdictions. In addition, in many countries outside the U.S., a new product must receive pricing and reimbursement approval prior to commercialization. This can result in substantial delays in these countries. Additionally, the product labeling requirements outside the U.S. may be different and inconsistent with the U.S. labeling requirements, negatively affecting our ability to market our products in countries outside the U.S.

In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we, or our commercial collaborator, fail to comply with applicable foreign regulatory requirements. In such an event, our ability, or our commercial collaborator's ability, to market to the full target market for our products will be reduced and the full market potential of our products may not be realized, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Section 503B Compounding

We plan to generate revenue from sales of our proprietary Sildenafil Cream formulation produced by Section 503B-registered outsourcing facilities, but we have no experience in this line of business and may not be successful in our efforts.

One aspect of our business strategy is to enter into licensing arrangements with outsourcing facilities through which we can generate revenue from sales of our proprietary Sildenafil Cream formulation produced by those outsourcing facilities under Section 503B. We have no experience in the compounded drugs market and we have never entered into arrangements with outsourcing facilities. We will be required to successfully identify and enter into satisfactory arrangements with one or more outsourcing facilities, and no assurances can be given that we will be successful in doing so on commercially reasonable terms or at all. Even if we are successful in this regard, we may not generate sufficient revenue to recover our costs. Establishing such arrangements could be expensive and time consuming, disrupt our other operations, require significant capital expenditures and distract management and our other employees from other aspects of our business.

We will be reliant on Section 503B-registered outsourcing facilities to produce our proprietary Sildenafil Cream formulation, and their failure to adequately perform their obligations could harm our reputation, business and financial condition.

If we are able to enter into arrangements with one or more outsourcing facilities, we will be reliant on them to compound and distribute our proprietary Sildenafil Cream formulation and to comply with applicable statutory and regulatory requirements, including FDA's cGMP regulations and related FDA guidance for drugs compounded at outsourcing facilities. We will also be reliant on suppliers that supply sildenafil citrate to the outsourcing facilities. We will not control or direct the compounding or distribution process used by these parties, and we will have no control over their ability to maintain adequate quality control, quality assurance and qualified personnel. These arrangements also involve other risks, including:

- the inability of third parties to consistently meet product specifications and quality requirements;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- third parties may not be able to appropriately execute necessary manufacturing procedures and other logistical support requirements;
- third parties may fail to comply with cGMP requirements and other FDA or other comparable regulatory requirements;
- breach, termination or non-renewal of agreements in a manner or at a time that is costly or damaging to us;
- inability to procure or maintain state licenses in those states into which our proprietary Sildenafil Cream formulations are shipped;
- third parties may not devote sufficient resources to our needs;
- the operations of third parties could be disrupted by conditions unrelated to our business or operations; and
- logistics carrier disruptions or increased costs that are beyond our control.

Adverse developments affecting the supply of sildenafil citrate or the compounding or distribution operations of parties involved in the compounding and distribution of our proprietary Sildenafil Cream formulation may result in lot

failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the availability of our proprietary Sildenafil Cream formulation. We may also have to undertake costly remediation efforts, or seek more costly supply, compounding and distribution alternatives.

Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, total or partial suspension of production, or issuance of a Form 483 or Warning Letter.

Our plan to bring our proprietary Sildenafil Cream formulation to market under Section 503B will subject us to a variety of new regulations and related potential liability.

We plan to enter into arrangements with one or more outsourcing facility(ies) to produce and distribute our proprietary Sildenafil Cream formulation under Section 503B. An outsourcing facility must meet certain conditions under Section 503B, including registering with the FDA, operating in compliance with the FDA's cGMP regulations and guidance, and is subject to FDA inspection. Outsourcing facilities have been subject to increased scrutiny of their compounding activities by the FDA and state governmental agencies. Governmental inquiries or actions or litigation brought against us or any of our suppliers or outsourcing facilities relating to our proprietary Sildenafil Cream formulation, whether or not such inquiry, action or litigation ultimately results in penalties, changes to our business practices or other consequences, could have an adverse effect on our reputation, business and financial condition.

We or any outsourcing facility with which we have a business relationship may also face allegations, litigation, and regulatory investigations under federal or state laws related to the promotion, advertising, fulfillment, distribution, and/or sale of our proprietary Sildenafil Cream formulation under Section 503B. Litigation and regulatory proceedings, and particularly the healthcare, pharmaceutical-related, consumer protection, data privacy and/or class action matters we could face, may be protracted and expensive, and the results are difficult to predict. Such litigation or regulatory proceedings and investigations, unexpected side effects or safety or efficacy concerns with our proprietary Sildenafil Cream formulation or related negative publicity could have an adverse effect on our reputation, business and financial condition.

Achieving and maintaining market acceptance of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B could be negatively impacted by perceived risks associated with compounded drugs.

Compounded drugs are not FDA-approved products; lawfully compounded drugs are specifically exempt from FDA approval pursuant to Section 503B(a). Some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, a compounded drug for a variety of reasons, including because it is not required to be, and has not been, approved for marketing and sale by the FDA. In addition, certain outsourcing facilities have experienced both facility and product quality issues and been the subject of negative media coverage and litigation, and the actions of these facilities have resulted in increased scrutiny of compounding activities. Our ability to generate revenue from sales of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B will be adversely impacted if we are unable to achieve and maintain market acceptance for it.

Sildenafil citrate must remain on the list of bulk substances that may be used in compounding under Section 503B, and if it were to be removed, we would be unable to offer our proprietary Sildenafil Cream formulation under Section 503B.

Sildenafil citrate is currently listed among those nominated substances for which bulk drug substance may be used in compounding by Section 503B-registered outsourcing facilities; the so-called "Category 1" list pending FDA's evaluation. However, we have no control over whether sildenafil citrate will remain on the list of bulk drug substance that may be used in compounding by outsourcing facilities or for how long. If sildenafil citrate is removed from the list, we would be unable to offer our proprietary Sildenafil Cream formulation via a Section 503B-registered outsourcing facility, and it could harm our reputation, business and financial condition.

In addition, a third party could request that the FDA remove sildenafil citrate from the list of bulk substances that may be used in compounding by Section 503B-registered outsourcing facilities. If removed from such list, outsourcing facilities would be prohibited from producing any compounded drug that includes sildenafil citrate, including our proprietary Sildenafil Cream formulation. For information regarding how the FDA intends to evaluate whether there exists a clinical need for compounding with a bulk drug substance, see "Regulation of Compounded Drugs," below.

If a compounded drug formulation provided by an outsourcing facility leads to patient injury or death, or results in a product recall, we may be exposed to significant liability and reputational harm.

The success of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B will depend to a significant extent upon perceptions of product quality. We could be adversely affected if the formulation is

subject to negative publicity. We could also be adversely affected if it or similar products sold by other companies, or any products sold by outsourcing facilities that produce our proprietary Sildenafil Cream formulation, prove to be, or are alleged or asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who takes a compounded drug, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper distribution or other uses of the compounded drug, any of which could result from human or other error. Any of these situations could lead to a recall of, or safety alert relating to, the compounded drug. Similarly, to the extent any of the ingredients used to produce a compounded drug have quality or other problems that adversely affect the finished compounded drug, its sales could be adversely affected. Because of our dependence upon perceptions of prescribing physicians and their patients, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B, any similar product sold by other companies, or related to compounded formulations generally, could have a material adverse impact on our reputation, business, and financial condition.

Risks Related to Employee Matters and Managing Our Growth

We have a relatively small number of employees to manage and operate our business.

As of March 28, 2025, we had 23 employees, of which 21 were full-time and two were part-time. Our focus on controlling our cash utilization requires us to manage and operate our business in a highly efficient manner, relying on consultants and other third-party service providers for product development and operational expertise we require, and to limit full-time personnel resources. With a small number of employees, our ability to supervise the service providers we engage, including our CMOs and CROs, may be constrained, which may impact the timing and quality of services we receive. No assurance can be given that we will be able to run our operations or accomplish all of the objectives we otherwise would seek to accomplish with the limited personnel resources we currently have.

In addition, due to our small workforce, if multiple employees were to become unable to work for a protracted period for any reason, or if they were to resign at roughly the same time, our business could suffer. Our ability to effectively manage and operate our business could become significantly impaired and our expenses could increase materially, including as a result of expenditures related to recruiting, hiring and training qualified new employees and engaging additional consultants and service providers to perform the job responsibilities of the employees on leave or who resign. If we or our collaborators or service providers experience staffing shortages, it may result in significant delays in our anticipated development program timelines.

If we fail to attract and retain management and other key personnel, we may not successfully complete development of, obtain regulatory approval for or commercialize our product candidates, or otherwise implement our business plan.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified managerial and key personnel. We depend highly on our senior management. Losing the services of our senior management, and our chief executive officer in particular, could impede, delay or prevent the development and commercialization of our product candidates, harm our ability to raise additional funds and negatively impact our ability to implement our business plan. If we lose the services of any of our senior management team, we might not find suitable replacements on a timely basis or at all, and our business could be materially harmed. We do not maintain “key man” insurance policies on the lives of any of our senior management employees.

We might not attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biopharmaceutical companies and other life sciences R&D organizations, particularly in the San Diego area where we are headquartered. In addition, our limited personnel and financial resources may result in greater workloads for our employees compared to those at companies with which we compete for personnel, which may lead to higher levels of employee burnout and turnover. Many of the other companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better opportunities for career advancement. If we cannot attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

New legal precedent, laws and regulations and increased levels of lawsuits by public company stockholders could make it costlier or more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract or retain qualified persons to serve as our senior management or on our board of directors.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates or technologies, which may limit our growth potential.

Our business development strategy involves identifying and acquiring or in-licensing potential product candidates or technologies. We assembled our current portfolio of product candidates through the acquisition of companies and assets and in-licensing transactions beginning in 2017. We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense.

These efforts may not be successful, including for reasons discussed in elsewhere in this Risk Factors section and also:

- we may fail to appropriately evaluate the potential risks and uncertainties associated with a transaction;
- there may be intense competition to acquire or in-license promising product candidates and technologies and many of our competitors have considerably more financial, development and commercialization resources than we have;
- we may not effectively integrate the acquired or in-licensed assets, businesses, personnel, intellectual property or business relationships;
- we may underestimate the development and regulatory approval challenges, costs and timelines and overestimate the market opportunity for the potential product candidates and technologies; and
- during development, the acquired or in-licensed product candidates may not prove to be safe or effective in their targeted indications.

We may fail to realize the anticipated value of any strategic transaction and the costs of a transaction may outweigh the benefits we realize from it. In addition, we have used shares of our common stock as consideration in strategic transactions and we may do so in the future, which may result in significant dilution to our stockholders. Any strategic transaction we pursue may not produce the outcomes and benefits we originally anticipated and may adversely impact our operating results and financial condition and be detrimental to our company in general.

Risks Related to Our Intellectual Property

If we and our licensors are unable to obtain and maintain sufficient intellectual property protection, competitors could develop and commercialize or make available products similar or identical to ours, which could significantly limit the commercial potential of our products and product candidates and materially harm our business, financial condition, results of operations, and prospects.

Our success depends in part on our ability, and the ability of our licensors, to obtain, maintain, enforce, and defend patent rights, proprietary know-how, and trademarks of sufficient scope in the U.S. and other countries with respect to our products, product candidates and proprietary technologies. If we are unable to obtain, maintain, enforce and defend sufficient intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed.

We depend heavily on patent rights and other intellectual property in-licensed to us from third parties to protect most of the products and technologies we develop. For some such rights, our third-party licensors control patent strategy and prosecution and we have little, if any, influence or control over such patent strategy and prosecution, and our licensors may not always act in our best interest.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability, and that of our licensors, to obtain or enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications. We or our licensors may not have been the first to file patent applications for these inventions.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent

application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We cannot be certain if any of the patents that cover our product candidates will be eligible to be listed in the Orange Book following a drug product marketing approval. The advantage of being listed in the Orange Book is that, under the Hatch-Waxman Act, any future generic applicant for any of our approved products needs to include a patent certification in their generic application with respect to each patent listed in the Orange Book for an approved product (referred to as the "listed drug") for which they are seeking approval. If the generic applicant believes that any of the patents in the Orange Book on the listed drug is invalid, unenforceable, or not infringed by their product, the generic applicant usually will file a "Paragraph IV" certification on that patent if they plan to challenge the patent. When a generic applicant files a Paragraph IV certification, they must provide the listed drug applicant (and the patent owner if different) a notice that they filed a generic application with the Paragraph IV certification. If, in reply to that notice, the listed drug holder files a patent lawsuit against the generic applicant within 45 days of the Paragraph IV notice, a 30-month automatic stay is imposed by the Hatch-Waxman Act on FDA during which FDA may not approve the generic application (unless the patent litigation is resolved in the generic applicant's favor). These 30-month stays are major protection available in the Hatch-Waxman Act for innovative drug makers. However, if our products are approved, but one or more of our patents are not listed in the Orange Book, generic firms that might seek approval of a generic version of our product would not have to "certify" in their generic drug applications as to any such unlisted patent. This could result in the absence of a 30-month stay and thus faster approval of some generic applications for our products.

Other companies or individuals may independently develop similar or alternative technologies or duplicate our technologies. This could enable our competitors to develop a competing product that avoids infringing our patents. In such an event, our competitors might be able to enter the market, which could significantly harm the commercial opportunity for our product candidates.

The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, products and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets.

As an example, the complexity and uncertainty of European laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which are subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

There is a substantial backlog of patent applications at the USPTO that may lead to delays in having patent applications examined by the USPTO. There can be no assurance that any patent applications relating to our products or methods will be issued as patents or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. We and our licensors may not obtain patent rights on products, treatment methods or manufacturing processes that we may develop or to which we may obtain license or other rights. Even if patents are issued to us and our licensors, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. It is possible that no patents will be issued from any pending or future patent applications owned by us or licensed to us. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license, including the patents we have licensed to date and any other patents we may license in the future. Conversely, in the future we may have to initiate litigation against third parties to enforce our intellectual property rights. The defense and enforcement of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others or require us to cease selling our future products.

In addition, many other organizations are engaged in research and product development efforts that may overlap with our products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods we are developing or considering for development. These rights may prevent us from commercializing technology, or they may require us to obtain a

license from the organizations to use the technology. We may not obtain any such licenses that may be required on reasonable financial terms, if at all, and there can be no assurance that the patents underlying any such licenses will be valid or enforceable. As with other companies in the pharmaceutical industry, we are subject to the risks that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our intellectual property rights if such activities were conducted in the U.S. and enforcing our intellectual property rights against such persons may be difficult or not possible.

Our patents and other intellectual property also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the U.S. or foreign jurisdictions, our business prospects could be substantially harmed.

In addition, because of funding limitations and our limited cash resources, we may not be able to devote the resources that we might otherwise desire to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already-issued patents.

Most of the products we are developing utilize active pharmaceutical ingredients that are not proprietary to us or our licensors and the patents and patent applications owned by us and our licensors intended to protect our products and product candidates relate to specific formulations, processes, methods of delivery, and/or uses, which may not afford sufficient protection against competitors.

The APIs in XACIATO, Sildenafil Cream, DARE-HRT1, DARE-VVA1, DARE-HPV, and other products we are developing are not proprietary to us or our licensors. There are generic drugs available with the same APIs. The patent protection we and our licensors may obtain and maintain for such product candidates are limited to specific formulations, processes, methods of delivery, and/or uses, which may not afford us sufficient protection against competitors. For example, competitors could offer products with the same API as our products in a different formulation or delivery system or for an indication that is outside the scope of our patented formulation, system or use. The commercial opportunity for our products could be significantly harmed if competitors are able to develop or make available alternative formulations with the same APIs or better delivery approaches compared with the products we develop.

We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights. The situations in which we may become party to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights, or that one of our trademarks or trade names infringes the third party's trademark rights; in such case, we would need to defend against such proceedings. The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than us because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace, our financial condition and our stock price. Patent litigation and other intellectual property proceedings may also consume significant management time.

If a competitor infringes upon our patent or other intellectual property rights, including any rights licensed by us, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. Our rights to enforce and defend patents we in-license depend upon the terms of our agreements with our third-party licensors, and in some cases, our licensors have the right to control patent enforcement litigation and defense against patent infringement litigation, and we have indemnification obligations for certain losses arising from third-party claims. We also have indemnification obligations under our out-license agreements for XACIATO and Ovaprene, which could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition. Our rights to indemnification by our licensors and licensees may not be adequate to compensate us for losses or the

potential loss of our ability to manufacture and sell products. If we were unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

We cannot guarantee that we or any of our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S., Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the U.S., applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S., EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our or our licensors' interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We or our licensors may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our or our licensors' determination of the expiration date of any patent in the U.S., the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our licensors' failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

From time to time, we or our licensors may identify patents or applications in the same general area as our products and product candidates. We or our licensors may determine these third-party patents are irrelevant to our business based on various factors including our or our licensors' interpretation of the scope of the patent claims and our or our licensors' interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our or our licensors' determinations. Further, while we or our licensors may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us or our licensors. We cannot guarantee that we or our licensors will be able to successfully settle or otherwise resolve such infringement claims. If we or our licensors fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We or our licensors might, if possible, also be forced to redesign our product candidates so that we or our licensors no longer infringe on the third-party intellectual property rights. Any of these events, even if we or our licensors were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We also rely upon trade secrets to protect our technology, product and product candidates, and trade secrets can be difficult to maintain and enforce.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to derive a competitive advantage for products we develop, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to maintain. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, we or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not have adequate remedies in respect of that disclosure. Enforcement of claims that a party illegally disclosed or obtained and is using trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, foreign courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

Our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors may be able to legally obtain products of ours and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our know-how, trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

We enter into confidentiality and nondisclosure agreements with our employees, CROs, CMOs, consultants, collaborators, sponsored researchers, and scientific and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party on our behalf or made known to the party by us during the course of the party's relationship with us. We also enter into intellectual property assignment agreements with our employees, consultants and certain other service providers, which generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored or may not effectively assign intellectual property rights to us. We have not entered into any non-compete agreements with any of our employees. We cannot guarantee that the confidential nature of our proprietary information will be maintained by our employees and others in the course of their future employment with or provision of services to a competitor. Enforcing a claim that a party illegally disclosed or obtained and is using our know-how, trade secrets or other proprietary information is difficult, expensive and time consuming and the outcome is unpredictable. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage for the products we develop, which could materially adversely affect our business, operating results and financial condition.

Provisions in our agreements with governmental agencies and non-profit organizations may affect our intellectual property rights and the value of our development programs to our company.

Certain of our product development activities have been funded, are being funded and may in the future be funded, by the U.S. government and/or not-for-profit organizations. Our agreements for these sources of funding include, and may in the future include, terms and conditions that affect our intellectual property rights. For example, under our CRADA with NICHD for the Phase 3 clinical study of Ovaprene, the U.S. government has a nonexclusive, nontransferable, irrevocable, paid-up right to practice for research or other government purposes any invention of either party conceived or first actually reduced to practice in the party's performance of the CRADA and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed. Under our subaward agreement with VentureWell, the federal government has a nonexclusive license to obtain access to and to share research results and data, as well as certain rights, including "march-in" rights, in intellectual property conceived, made, created, developed or reduced to practice in our performance of the research activities and objectives relating to advancement of our DARE-HPV program specified in the subaward agreement, pursuant to and in accordance with the Bayh-Dole Act of 1980. During the term of the subaward agreement and for three years thereafter, we are subject to certain restrictions on foreign access to the intellectual property and other technology developed by or for us in or for the provision of such services, including restrictions on our sale or other transfer of such technology to a foreign firm or institution (which would include a sale of our company and a sale or licensing of such technology, but not sales of products or components) without the prior approval of the federal agency providing funding for the subaward agreement.

The U.S. federal government retains certain rights in inventions produced with its financial assistance. Under the Bayh-Dole Act, the federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in" rights. March-in rights allow federal agencies, in specified circumstances, to require the recipient of federal funding (the contractor) or successors in title to the patent to grant a nonexclusive, partially exclusive or exclusive license to a third party if it determines that (i) adequate steps have not been taken to achieve practical application of the invention, (ii) government action is necessary to meet public health or safety needs, (iii) government action is necessary to meet requirements for public use under federal regulations or (iv) unless the requirement has been waived, the contractor has failed to substantially manufacture in the U.S. any product embodying the subject invention that is intended for U.S. commerce. If the contractor or its successor refuses to do so, the government may grant the license itself. The federal government also has the right to take title to these inventions if the contractor or its successor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. To date, no federal agency has ever exercised march-in rights; however, the Biden administration announced that it viewed march-in rights as a legitimate means for the government to address rising pharmaceutical costs and future use of march-in rights by the government is uncertain. Any exercise by the government of march-in rights could harm our competitive position, business, financial condition, results of operations and prospects.

Under our grant agreements with the Foundation, we agreed to make products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the respective

projects funded by the respective grants (referred to as Funded Developments), available and accessible at an affordable price to people most in need within developing countries, and to promptly and broadly disseminate the knowledge and information gained from the project funded by the grant (referred to as the Global Access Commitment). In connection with the Global Access Commitment, under the agreement, we also granted the foundation that awarded the grant a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and essential background technology (referred to as the Humanitarian License). We are required to ensure that the Humanitarian License survives the assignment or transfer of Funded Developments and essential background technology. Our obligations under the Global Access Commitment and the Humanitarian License may limit the value to us of the Funded Developments.

Risks Related to Our Business Operations and Industry

Disruptions at the FDA, NIH, SEC and other government agencies, including due to lack of funding, changes in leadership, significant personnel turnover, or diminished staffing, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and hinder our ability to raise additional capital.

Twice in the past decade, the previous appropriations legislation deadline was reached and Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U.S. government shutdowns that caused federal agencies to halt non-essential operations. The federal government came close to another shutdown several times in recent years. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. A federal government shutdown could prevent or delay staff at federal agencies from performing key functions that may adversely affect our business.

In addition, considerable uncertainty exists regarding how federal government policy changes and budget decisions will unfold, including the regulatory and spending priorities of the new U.S. presidential administration and Congress, and what challenges potential policy changes and budget reductions will present for us and our industry generally. Measures being implemented by the new U.S. presidential administration are expected to significantly impact federal regulatory agencies, such as by reducing funding to or restructuring such agencies. For example, in the first quarter of 2025, the new U.S. presidential administration began terminating federal government employees and federal agencies were directed to develop plans for large-scale reductions in force and reorganization. As a result, agencies throughout the federal government may experience mass layoffs, as well as a significant number of voluntary departures. The impact of these changes at federal government agencies with which we interact is uncertain at this time, however, mass layoffs and large-scale voluntary departures, in particular at the FDA, NIH, ARPA-H and SEC, could adversely impact our company. For example, if it experiences significant workforce reduction or turnover, the FDA in the future may be unlikely to meet its application review goals or be available for timely interactions regarding our product development plans, which could delay our ability to advance clinical development of our product candidates or obtain marketing approvals. The ability of the FDA to review and approve new product applications or take action with respect to other regulatory matters can be affected by a variety of factors, including funding levels, ability to accept the payment of user fees, ability to hire and retain key personnel, and statutory, regulatory and policy changes. Disruptions at the FDA may delay meetings and other communications with or on-site inspections by agency staff necessary to progress development of our product candidates and may slow the time necessary for acceptance, review and approval of applications to commence clinical studies or to market a new product in the U.S. By way of further example, disruptions at the NIH, including its various institutes and centers, such as NICHD, could delay or prevent providing or processing new grant awards to fund research and development activities and disrupt staff's work and other activities or funding under active grant/cooperative agreements. As discussed elsewhere in this report, including in this Risk Factors section, changes and disruptions at HHS agencies could result in delays or disruptions to our Phase 3 clinical study of Ovaprene and advancement of our DARE-HPV program. Moreover, reduced funding levels or leadership and policy changes at HHS agencies could negatively impact our ability to obtain additional grant awards or other non-dilutive federal funding opportunities.

Disruptions at the SEC could prevent or delay SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. For example, if a federal government shutdown halts non-essential SEC operations for an extended period during which we do not have an effective shelf registration statement, it may negatively impact our ability to raise additional capital through registered offerings of our securities.

If a prolonged U.S. government shutdown or other event or condition occurs that prevents or significantly delays the FDA, NIH, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, or if an agency is restructured or experiences a significant reduction in funding, leadership changes,

workforce reduction or employee turnover, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, which could have a material adverse effect on our business.

Business interruptions resulting from public health crises, natural disasters or telecommunication and electrical failures may materially and adversely affect our business, operating results and financial condition.

We may experience significant business disruptions as a result of a public health emergency, natural or manmade disaster, act of terrorism, war, or telecommunications or electrical failure that impacts our facilities or employees, or those of the third parties on which we rely for key business activities. The effects of such events or conditions may materially and adversely affect our product development activities in the future, including as a result of:

- difficulties and delays in clinical study site initiation, including due to diversion of healthcare resources away from conducting clinical studies or delays in IRB review and approval of clinical study protocols;
- difficulties and delays in recruiting and enrolling clinical study participants and conducting follow-up visits;
- interruption of key clinical study activities, such as study site and data monitoring, due to operational closures or disruptions at our CROs or study sites or limitations on travel or in-person gatherings;
- staff disruptions and turnover internally or at our CMOs, CROs, clinical study sites, collaborators or other third parties on which we rely, either directly or indirectly as a result of reallocation of resources, illness, government mandates or other changes in terms of employment;
- difficulties and delays in production of clinical trial materials and commercial product, including due to supply chain disruptions or resource constraints or reallocation on the part of our CMOs and raw materials suppliers;
- interruptions in U.S. or global shipping that may affect the transport and delivery of raw materials, clinical study materials and commercial product;
- imposition of new or increased tariffs, sanctions, import/export controls or other trade policies that significantly increase the costs of the components and raw materials used in the production of XACIATO or our product candidates;
- changes in local regulations in response to a public health emergency or other emergency situation that may require changes in the ways our clinical studies are conducted, require us to discontinue a clinical study, or make it more difficult for commercial and medical affairs field teams to call on or otherwise access healthcare providers;
- patient delays in seeking or receiving treatment, either due to fear of infection or inaccessibility of healthcare providers;
- delays in interactions with the FDA or a foreign regulatory authority necessary to advance clinical development of our product candidates, or delays in their review process and timing of potential approval of our product candidates, including delays in pre-approval manufacturing or clinical study site inspections;
- difficulties and delays in establishing or maintaining strategic commercial or development collaborations due to the reallocation of resources or shifting business strategies of collaborators or potential collaborators away from the women's health market in general or our areas of focus within women's health in particular; or
- disruption and volatility in the financial markets which negatively impacts our access to additional capital or stock price.

For example, in March 2020, the COVID-19 pandemic began to impact the global economy. The COVID-19 pandemic disrupted our product development activities and the business activities of third parties on which we rely. The COVID-19 pandemic contributed to a slower than anticipated pace of enrollment of participants in our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream as a result of operational restrictions or closure of certain study sites due to their adherence to governmental guidelines intended to reduce the spread of COVID-19. The COVID-19 pandemic also caused us to prioritize advancement of certain of our development programs over others, or certain development activities within a program over others, due to anticipated or actual difficulties and delays in recruiting clinical study sites and participants and obtaining clinical trial materials and supplies.

The strategies we implement designed to mitigate the effects or potential effects on our business of a public health emergency such as the COVID-19 pandemic, a natural or manmade disaster, act of terrorism, war or telecommunications or electrical failure that impacts our facilities or employees or those of third parties on which we rely may not be effective. The occurrence of such an event or condition could cause significant delays in the timelines for our clinical studies, our regulatory submissions or potential marketing approvals of our product candidates, substantially increase our development costs, and delay or contribute to delays in the commercial launch of any approved product or market acceptance of the product. The longer such an event or condition persists, the greater the potential for significant adverse impacts to our business operations and those of the CROs, CMOs, commercial collaborators, and other third-party service providers and vendors on which we depend to, among other things, conduct our clinical and nonclinical studies, supply our clinical trial materials, assist with regulatory affairs necessary to advance and seek regulatory approval for our programs, and market, sell and distribute our products, if approved for commercial sale.

Public health emergencies, natural or manmade disasters, acts of terrorism, war or telecommunications or electrical failures may also have the effect of heightening many of the other risks and uncertainties described in this Risk Factors section.

Product liability lawsuits against us could cause us to incur substantial liabilities.

We face an inherent risk of product liability exposure as a result of testing of our product candidates in human clinical trials and will face an even greater risk following commercial launch of a product we develop. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities or be required to limit commercialization of our products. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any marketed product;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- termination of product development or commercial collaborations;
- loss of revenue;
- withdrawal of clinical study participants and delays in commencement or completion of clinical studies;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients or clinical study participants;
- diversion of our management's time and other resources from pursuing our business strategy; and
- a decline in our stock price.

We carry product liability insurance that we believe to be adequate for our clinical testing and product development programs and in connection with XACIATO. However, insurance coverage is increasingly expensive, and it may be difficult to obtain adequate product liability insurance in the future. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of any of our product candidates, if approved for commercial sale. We also have indemnification obligations to our commercial and other collaborators. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our current or future employees, clinical investigators, commercial collaborators or service providers may engage in misconduct or other improper activities, including non-compliance with laws and regulatory standards.

We may become exposed to the risk of employees, clinical investigators, commercial collaborators, CMOs, CROs, consultants or other vendors engaging in fraud or other misconduct. Misconduct by our employees or third parties on which we rely for the development and commercialization of our products and product candidates could include intentional failures, such as failures to: (1) comply with FDA or other regulators' requirements, (2) provide accurate information to such regulators, (3) comply with clinical and nonclinical research standards and manufacturing standards established by us and/or required by the FDA or other laws and regulations, or (4) comply with SEC rules and regulations. Sales, marketing and business arrangements in the health care industry are subject to extensive

laws, regulations and industry guidance intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by current or future employees, clinical investigators, commercial collaborators, CROs, consultants or other vendors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory or civil sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant adverse effect on our business, including the imposition of significant fines or other sanctions, and reputational harm.

The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act.

Health care providers and third-party payors play a primary role in the recommendation and prescription of drug products and medical devices that are granted marketing approval. Our arrangements with health care providers, commercial collaborators, principal investigators, consultants, third-party payors, customers and other organizations may expose us to broadly applicable fraud and abuse and other health care laws and regulations in the U.S. Health care fraud and abuse regulations are complex, and even minor irregularities can give rise to claims that a statute or prohibition has been violated. The laws that may affect our operations include:

- the federal Anti-Kickback Statute (and comparable state laws), which prohibits, among other things, any person from knowingly and willfully offering, providing, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with health care companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- federal and state civil and criminal false claims laws, including the civil False Claims Act which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the U.S. Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;
- federal, civil and criminal statues created under HIPAA (and similar state laws), which prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the Physician Payments Sunshine Act, enacted as part of the ACA, which, among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report to CMS, on an annual basis, information related to payments and other transfers of value to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non-physician health care practitioners, and teaching

hospitals, as well as ownership and investment interests held by physicians and their immediate family members in such manufacturers;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose specified requirements relating to the privacy, security and electronic exchange of individually identifiable health information, or "protected health information" when subject to HIPAA. Among other things, HITECH makes some of HIPAA's privacy and all of HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. "Covered entity" or entities that must comply with HIPAA, include certain health care providers, health plans, and health care clearinghouses. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and third parties unlawfully in possession of protected health information, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions; and
- the U.S. Foreign Corrupt Practices Act, which prohibits U.S. organizations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers of value to non-U.S. officials, which in many countries, could include interactions with certain health care professionals.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations.

The risk of violation of, and subsequent investigation and prosecution for violations of, the laws described above may be mitigated through the implementation and maintenance of compliance programs by us and our commercial collaborators and other third parties on which we rely for important aspects of development or commercialization of our products and product candidates, but these risks cannot be eliminated entirely. Ensuring that our current and future business operations and arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other health care laws and regulations. If we or our operations, or those of a commercial collaborator or other third party on which we rely for development or commercialization of our products and product candidates, are found to be in violation of any of the laws described above or any other governmental regulations that apply to us or that third party, we may be subject to significant civil, criminal and administrative penalties, including monetary damages, fines, individual imprisonment, disgorgement, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, health care reimbursement or other government programs, including Medicare and Medicaid, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and/or the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

If regulatory authorities challenge our activities, or those of a commercial collaborator or other third party on which we rely, under these laws, any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any investigation of us or the third parties with whom we contract, including a commercial collaborator, regardless of the outcome, would be costly and time consuming, and may negatively affect our results of operations and financial condition.

Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our collaborators or third-party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information, subject us to significant financial loss, and expose us to liability, any of which could adversely affect our business and our reputation.

We utilize information technology systems and networks in the ordinary course of our business to process, transmit and store sensitive data, including confidential information, intellectual property, and personally identifiable information of our employees, consultants and others. As the use of digital technologies has increased, cyber incidents, including deliberate attacks (such as the deployment of harmful malware and other malicious code, ransomware, denial of service, social engineering, and other attempts to gain unauthorized access to computer systems and networks), have increased in frequency and sophistication, and have become increasingly difficult to detect. These threats pose a risk to the security of our systems and networks and those of our collaborators and third-party service providers, including our CMOs and CROs for our clinical studies, which store sensitive or confidential data of ours, and could compromise the confidentiality, availability and integrity of such information which may be vital

to our operations and business strategy. A successful cyber-attack could cause serious negative consequences for us, including, without limitation, the disruption of our operations, the misappropriation or destruction of our confidential information and sensitive data, including clinical trial data, corporate strategic plans and financial information, and the misappropriation of other assets, including our cash. Organizations and governmental bodies with far greater resources than ours dedicated to cybersecurity have proven vulnerable to cyber-attacks. There can be no assurance we will succeed in preventing cybersecurity breaches or successfully mitigate their effects. In March 2023, we became aware that we had been subject to a criminal fraud commonly referred to as “business email compromise fraud.” The incident involved unauthorized access to an employee’s email account by a third-party impersonator and resulted in an electronic payment of approximately $0.4 million intended for a vendor being fraudulently misdirected to unknown parties. We retained a third party to assist in our investigation of the incident and implementation of remedial measures, including enhancements to our controls relating to electronic payments to third parties. Approximately $0.2 million of the fraud loss was covered by insurance. We do not believe this incident had or will have a material impact on our business, financial condition or results of operations. However, cyber-related criminal activities continue to evolve and increase in frequency and sophistication, including as a result of advancements in generative artificial intelligence technology, and our security measures and controls may not be successful in preventing further cyber-related crimes.

Despite implementing security measures, any of the information technology systems belonging to us or our collaborators and third-party service providers, including our CMOs and CROs for our clinical studies, and the sensitive and confidential information contained within them are vulnerable to damage or interruption from computer viruses and other malware, unauthorized access, including as a result of employee error (e.g., phishing or spoofing scams) or malfeasance, service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failure. We rely on third-party service providers and technologies for our data processing-related activities, including without limitation third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We rely on these third parties to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. However, our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate security measures in place. In addition, we do not have our own information technology department or personnel and rely on third-party information technology consultants to assist our management in assessing, identifying and managing our cybersecurity risks. We do not control these third parties and they may fail to perform as expected. Moreover, the shift to remote working arrangements and the prevalent use of mobile devices that access sensitive or confidential information increases the risk of data security breaches. Technology security systems and other security measures in employees’ homes or other places they may work may not be as robust and more vulnerable to cybersecurity attacks. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party collaborators’ or service providers’ operations could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive or confidential information, or that of our employees, collaborators, service providers and participants in our clinical studies. A security incident or other interruption could disrupt our ability (or that of third parties upon which we rely) to conduct our business operations and could divert significant resources to remedy or mitigate the damage caused. For example, if clinical or nonclinical study data is lost or becomes compromised, it could result in delays in our product development and regulatory approval efforts and significantly increase our costs due to additional time and resources necessary to recover and verify, or potentially reproduce, the data. In addition, a security breach or privacy violation that leads to disclosure of personally identifiable information or protected health information could require us to make notifications to the public as well as regulatory authorities, harm our reputation, subject us to audit, investigation, steep fines and administrative penalties and mandatory corrective action. A data breach could also require us to verify the correctness of database contents and subject us to litigation, including class action lawsuits, or other liability under laws and regulations that protect personal data, consumer protection and other laws. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the internet, face the risk of systemic failure, which could disrupt our operations. If any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability, our product development programs and competitive position may be adversely affected, the further development of our product candidates may be delayed, and the manufacture and sale of any approved products may be impaired.

The costs related to significant security breaches or disruptions could be material, and, as was the case with the fraud discovered in March 2023, our insurance coverage may not cover all the losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations and product development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Moreover, if the information technology systems of our third-party

collaborators, service providers or vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event.

Our business may be adversely affected by general conditions in the global economy and financial markets and geopolitical tensions and events.

Various macroeconomic factors could adversely affect our business, our results of operations and financial condition, including a U.S. government shutdown, delay or failure of the U.S. government to raise the federal debt ceiling, an increased rate of inflation, rising interest rates, adverse developments affecting financial institutions or the financial services industry, recessionary concerns and overall unfavorable economic conditions and uncertainties, including those resulting from geopolitical events, including the wars in Ukraine and the Middle East and strained relations between the U.S. and a number of foreign countries; international economic sanctions, including those imposed on Russia; new or increased tariffs and other barriers to trade; climate change concerns; or public health emergencies, including the COVID-19 pandemic. U.S. government actions to reduce the federal deficit, or its delay or failure to raise the federal debt ceiling, may result in reduced funding for government-funded or subsidized health programs or require the federal government to stop or delay making payments on its obligations under such programs, which could impact sales of our products covered under such programs, if any, and negatively affect our operating results. Interest rates and the ability to access credit markets could adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute our products, if and when commercially available. Similarly, unfavorable or uncertain macroeconomic factors could affect the ability of our current or potential future collaborators, third-party service providers or suppliers, including sole source or single source manufacturers or suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply our clinical trial material and products or commercialize our products, if and when approved. Failure by any of them to remain in business or allocate adequate resources to our products and product candidates could have a material adverse effect on our efforts to develop and obtain regulatory approvals for our product candidates and generate revenue from any approved products.

We expect to continue to incur substantial costs and demands on management time to comply with laws and regulations affecting public companies.

We incur and expect to continue to incur significant legal, accounting and other expenses as a public reporting company. We expect that these expenses will increase if and when we become an “accelerated filer,” as defined in rules adopted by the SEC under the Securities Exchange Act of 1934. Generally, we will become an accelerated filer if our public float as of the last business day of June is $75 million or more and we reported annual revenues of $100 million or more for our most recently completed fiscal year. Regardless of whether we become an accelerated filer, we may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the corporate governance, disclosure and other reporting requirements of being a public company, and our management and other personnel, of whom we have a small number, will need to continue to devote substantial time towards compliance matters and initiatives.

For example, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we must furnish a report annually by our management on the effectiveness of our internal control over financial reporting, and performing the system and process documentation and evaluation necessary to issue that report requires us to incur substantial expense and expend significant management time. If and when we are an accelerated filer, we will also have to obtain an attestation report on our internal control over financial reporting by our independent registered public accounting firm, which may substantially increase compliance costs. Recent SEC rules and rulemaking initiatives, such as those regarding pay versus performance, compensation clawback, and cybersecurity disclosure requirements, may result in significant additional time and expense devoted to compliance initiatives.

We are a smaller reporting company and a non-accelerated filer and the reduced disclosure requirements available to us may make our common stock less attractive to investors.

The SEC established the smaller reporting company, or SRC, category of companies in 2008, and expanded it in 2018, in an effort to provide general regulatory relief for smaller companies. SRCs may choose to comply with scaled financial and non-financial disclosure requirements in their annual and quarterly reports and registration statements relative to non-SRCs. In addition, companies that are not “accelerated filers” can take advantage of additional regulatory relief. Whether a company is an accelerated filer or a SRC is determined on an annual basis. For so long as we qualify as a non-accelerated filer and/or an SRC, we will be permitted to and we intend to rely on some or all of the accommodations available to such companies. These accommodations include:

- not being required to provide an auditor’s attestation of management’s assessment of internal control over financial reporting required by Section 404(b) of the Sarbanes-Oxley Act of 2002;

- reduced financial disclosure obligations, including that SRCs need only provide two years of financial statements rather than three years; a maximum of two years of acquiree financial statements are required rather than three years; fewer circumstances under which pro forma financial statements are required; and less stringent age of financial statements requirements;
- reduced non-financial disclosure obligations, including regarding the description of their business, management's discussion and analysis of financial condition and results of operations, market risk, executive compensation, policies governing transactions with related persons, and corporate governance; and
- later deadlines for the filing of annual and quarterly reports compared to accelerated filers.

We will continue to qualify as a SRC and non-accelerated filer for so long as (a) our public float is less than $75 million as of the last day of our most recently completed second fiscal quarter or (b) our public float is $75 million or more but less than $700 million and we reported annual revenues of less than $100 million for our most recently completed fiscal year.

We may choose to take advantage of some, but not all, of the available accommodations. We cannot predict whether investors will find our common stock less attractive if we rely on these accommodations. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

Our ability to use net operating loss carryforwards and other tax attributes to offset taxable income may be limited.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. At December 31, 2024, we had substantial federal and state net operating loss, or NOL, carryforwards. However, our federal NOL carryforwards and other tax attributes may not be available to offset future taxable income because of restrictions under U.S. tax law, including limitations due to ownership changes that occurred previously or that could occur in the future, and similar limitations may apply under state tax laws. In addition, under legislation enacted by California in 2024, generally, there is a suspension of the NOL deduction for tax years 2024 through 2026 for taxpayers with net business income or modified adjusted gross income of $1 million or more, and a limit of $5 million of business credits on the aggregate use of otherwise allowable business tax credits that any taxpayer could claim for tax years beginning 2024 through 2026. For these reasons, we may not be able to realize a tax benefit from the use of our NOL carryforwards and other tax attributes, even if we attain profitability. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. See Note 8 "Income Taxes" to the accompanying consolidated financial statements for more information about limitations on our ability to use our NOL carryforwards and other tax attributes.

Risks Related to Ownership of Our Common Stock

The price of our common stock may rise and fall rapidly, substantial price fluctuations may occur regardless of developments in our business or our operating performance, and you could lose all or part of your investment as a result.

The stock market in general, and the market for biopharmaceutical companies in particular, have experienced significant volatility, which has often been unrelated to the operating performance of particular companies. The stocks of small cap and microcap biopharmaceutical companies like ours tend to be highly volatile. Our common stock has experienced extreme trading price and volume fluctuations in the past, including fluctuations that have been unrelated or disproportionate to developments in our business and our operating performance, and we expect that our stock price will continue to experience high volatility. The market price for our common stock may be influenced by a variety of factors, some of which are beyond our control or are related in complex ways, including:

- significant developments with our product development programs, such as actual or anticipated changes to development and approval timelines, results from any clinical trial, unanticipated serious safety concerns, suspension or discontinuation of a program, initiation of a new program and communications or decisions from the FDA or other regulatory authorities relating to applications we submit for clinical trials or marketing approval of our product candidates;
- announcements of capital raising transactions, including sales of our common stock or securities convertible into or exercisable for shares of our common stock by us, or expectation of additional financing efforts;

- the amount of our cash;
- the level of actual or anticipated expenses related to development of our product candidates, and in particular our clinical-stage development programs;
- announcements relating to strategic collaborations or alliances or significant licenses, acquisitions or dispositions of assets or capital commitments by us or our competitors or companies perceived to be economically linked to us;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- significant developments with third-party products or product development programs perceived as competitive to ours, such as results of clinical trials, unanticipated serious safety concerns, suspension or discontinuation of a program, significant communications or decisions from the FDA or other regulatory authorities, introduction of new product candidates or new uses for existing products, commercial launch and product sales;
- significant business disruptions, including as a result of cybersecurity incidents, geopolitical events, including military conflicts, war, terrorism or economic conflicts, or natural disasters such as earthquakes, typhoons, floods and fires or public health emergencies such as the COVID-19 pandemic;
- events or conditions that affect the financial markets or U.S. or global economy in general, including geopolitical conflicts, potential or actual U.S. government shutdown or failure to raise the federal debt ceiling, economic slowdown or recession, increased inflation, and rising interest rates;
- regulatory or legal developments in the U.S. and other countries;
- changes in the structure of health care payment systems;
- developments or trends in the biopharmaceutical or women's health care industries;
- period to period fluctuations in our financial results;
- recommendations or reports issued by securities research analysts;
- increased selling by our stockholders, as well as the overall trading volume of our common stock; and
- the other factors described in this Risk Factors section.

In the past, following periods of volatility in companies' stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

If we fail to regain and maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

Our common stock is listed on The Nasdaq Capital Market. In August 2024, we received a letter from Nasdaq notifying us that we do not meet the requirement in Nasdaq Listing Rule 5550(b)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(2) requires a company listed on Nasdaq to maintain a minimum market value of listed securities of $35.0 million, which we refer to as the "Minimum MVLS Rule." We were provided an initial period of 180 calendar days, or until February 10, 2025, to regain compliance with the Minimum MVLS Rule.

On February 13, 2025, Nasdaq's Listing Qualifications Department notified us that because we did not regain compliance with the Minimum MVLS Rule by February 10, 2025, our common stock is subject to delisting from Nasdaq unless we timely request a hearing before the Nasdaq Hearing Panel (the "Panel").

We requested a hearing before the Panel, which request stayed the delisting of our common stock pending the decision of the Panel following the hearing and the expiration of any extension period that may be granted by the Panel. The hearing was held on March 25, 2025. Pursuant to published Nasdaq guidance, the Panel typically issues decisions within 30 days of the hearing.

There can be no assurance that the Panel will grant us any extension period within which to regain compliance with the Minimum MVLS Rule, or if any extension period is granted, that we will regain compliance with the Minimum MVLS Rule within such extension period, or that we will be able to satisfy all other continued listing requirements of The Nasdaq Capital Market and maintain the listing of our common stock on The Nasdaq Capital Market even if we regain compliance with the Minimum MVLS Rule. For example, until we regained compliance on

July 18, 2024, we were not in compliance with the continued listing standard commonly referred to as the minimum bid price rule since July 19, 2023.

The suspension or delisting of our common stock, for whatever reason, could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the suspension or delisting of our common stock, for whatever reason, may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

The sale of our common stock in ATM offerings or under our equity line arrangement may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline.

We have used at-the-market, or ATM, offerings to fund a significant portion of our operations in prior years, and we may continue to use ATM offerings to raise additional capital in the future. For example, in 2021, we sold an aggregate of approximately 3.0 million shares of our common stock in ATM offerings. We sold substantially fewer shares in ATM offerings in 2022 and 2023 and to date in 2024, however, we may sell significant amounts of shares in ATM offerings again in the future. In addition, we may sell up to approximately $14.5 million in shares of our common stock under our equity line arrangement. The purchase price for the shares we may sell under our equity line arrangement will vary based on the market price of our common stock at the time we initiate a sale. While sales of shares of our common stock in ATM offerings and under our equity line arrangement may enable us to raise capital at a lower cost compared with other types of equity financing transactions; such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline.

The exercise of our outstanding warrants and options as well as the issuance of shares pursuant to future equity awards under our stock incentive plan may result in significant dilution to our stockholders.

As of December 31, 2024, we had outstanding warrants to purchase up to approximately 1.3 million shares of our common stock at a weighted average exercise price of $7.49 per share, outstanding options to purchase up to approximately 0.9 million shares of our common stock at a weighted average exercise price of $14.58 per share, and approximately 0.5 million shares of our common stock remained available for future issuance under our stock incentive plan. The exercise of a significant portion of our outstanding warrants and options and the issuance of shares of our common stock pursuant to future equity awards under our stock incentive plan may result in significant dilution to our stockholders.

Substantial future sales of our shares of common stock, or the perception that such sales could occur, may cause the price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, may adversely affect the trading price of our common stock, and may make it more difficult for existing stockholders to sell their shares of our common stock at a time and price they deem appropriate. We are unable to predict the effect that such sales may have on the trading price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity or equity-linked securities in the future at a time and at a price that we deem appropriate.

Shares underlying outstanding warrants represent approximately 14% of the outstanding shares of our common stock as of March 28, 2025, and the underlying shares generally may be freely sold into the public market following exercise of the warrants by the warrant holders. In addition, the issuance of all of the approximately 0.9 million shares of our common stock underlying outstanding options and the approximately 0.5 million shares of our common stock that remained available for future issuance under our stock incentive plan as of December 31, 2024 have been registered under the Securities Act and such shares if, and when issued, can be freely sold in the public market, except to the extent they are held by an affiliate of ours, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act.

Almost all of our outstanding warrants have exercise periods that extend into December 2028 or March 2029 and, as of December 31, 2024, our outstanding options had a weighted average remaining contractual exercise period of approximately 6.7 years. Accordingly, the potential adverse market and price pressures resulting from these

sales, or the perception that such sales could occur, may continue for an extended period of time and continued negative pressure on the trading price of our common stock could have a material adverse effect on our ability to raise additional capital through equity or equity-linked financings.

In addition, our Restated Certificate of Incorporation, as amended, authorizes us to issue up to 240.0 million shares of our common stock. Subject to limitations imposed by Nasdaq or such other securities exchange on which our securities may be listed, authorized shares of our common stock that are not issued and outstanding or reserved for issuance may be issued without stockholder approval at any time, in the sole discretion of our board of directors, and as of December 31, 2024, only approximately 8.7 million shares were issued and outstanding or reserved for issuance. If, in the future, we issue additional shares of common stock, warrants or other equity or equity-linked securities in one or more transactions, at prices and in a manner we determine from time to time, in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise, any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We may issue preferred stock with terms that could dilute the voting power or reduce the value of our common stock.

Our Restated Certificate of Incorporation, as amended, authorizes us to issue, without stockholder approval, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common stock respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of our common stock.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our shares.

We have never declared or paid cash dividends on any shares of our capital stock. We currently plan to retain all of our future earnings, if any, and all cash received from the sale of securities, the sale of assets or a strategic transaction to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders for the foreseeable future.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our Restated Certificate of Incorporation, as amended, our Third Amended and Restated By-Laws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions might frustrate or prevent any attempts by our stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of directors to be changed only by resolution of the board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize the board to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board; and
- require the approval of the holders of at least 75% of the votes that all stockholders would be entitled to cast in any annual election of directors or class of directors to amend or repeal our by-laws or certain provisions of our charter.

In addition, we are governed by Section 203 of the Delaware General Corporate Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of its voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

Provisions in our by-laws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Third Amended and Restated By-Laws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders; provided that, the exclusive forum provision will not apply to actions or suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. If any action that is required under our by-laws to be brought against us in Delaware is filed by a stockholder in a court other than a court located within Delaware, the stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within Delaware in connection with any action brought in any such court to enforce our Delaware forum selection provision and (ii) having service of process made upon the stockholder in any such enforcement action by service upon that stockholder's counsel, as agent for the stockholder. In addition, our by-laws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to these provisions.

Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act. We believe the forum selection provisions in our by-laws may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against us and/or our directors, officers and employees as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers or employees. The enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a future court could find the choice of forum provisions contained in our by-laws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our by-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

If we fail to attract or maintain securities analysts to publish research on our business or if they publish or convey negative evaluations of our business, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our common stock could decline. As of the date of this report, to our knowledge, five analysts cover our company. If one or more of these analysts cease coverage or fail to regularly publish reports on our business, we could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

As is the case for other companies in our industry, we may be the target of cyberattacks and other cyber incidents and, therefore, cybersecurity is an important element of our overall enterprise risk management, or ERM, program. Our management performs a semi-annual assessment of enterprise-wide risks to help assess, identify, and manage existing and emerging risks for our company, including cybersecurity risks. Through our ERM program we

assess the characteristics and circumstances of the evolving business environment at the time and seek to identify the potential impacts to our company of a particular risk.

Primary responsibility for assessing, identifying, and managing our cybersecurity risks rests with our management. To assist our management with such responsibility, we engage and consult with an external third party information technology consultant who reports to our Chief Accounting Officer. We also perform an annual cybersecurity assessment designed to help improve the systems and processes we have implemented designed to safeguard our information assets and operational integrity from cyber threats, protect employee information from unauthorized access or attack, as well as secure our networks and systems. Network and information systems and other technologies, including those related to our network management, are important to our business activities. As a result, we have multiple layers of security designed to detect and deter cybersecurity incidents. As part of our overall ERM program, we monitor and test our safeguards and train our employees on these safeguards, in certain instances with the assistance of our external third party information technology consultant. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings. We also maintain an incident response plan designed to respond to, mitigate and remediate cybersecurity incidents according to a defined set of severity ratings based on the potential impact to our business, information technology systems, network or data, including data held or information technology services provided by third-party vendors or other service providers.

As of the date of filing this report, we do not believe there are any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

For additional information regarding risks from cybersecurity threats, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K.

Governance

Our board of directors administers its cybersecurity risk oversight function through its audit committee. The audit committee is responsible for overseeing our policies, practices and assessments with respect to cybersecurity, and provides periodic updates to our board of directors. The audit committee receives periodic updates from management and our external third party information technology consultant regarding the effectiveness of the systems and processes we have implemented designed to safeguard our information assets and operational integrity from cyber threats, protect employee information from unauthorized access or attack, as well as secure our networks and systems, and regarding other cybersecurity matters, including the results from cybersecurity systems testing and any recent cybersecurity incidents and related responses. Our audit committee is also notified between such updates as soon as practicable regarding significant new cybersecurity threats or incidents. The audit committee also receives a report on cybersecurity matters and related risk exposures at least semi-annually from our Chief Accounting Officer. The chair of our audit committee has a National Association of Corporate Directors Carnegie Mellon University CERT Certification in Cybersecurity Oversight.

ITEM 2. PROPERTIES

We lease real property to support our business. We believe that the real property we lease is in good operating condition, meets our current needs and that we will be able to renew our lease when needed on acceptable terms or find alternative facilities. See Note 11 "Leased Properties" to the accompanying consolidated financial statements for more information about our real property leases.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversions of management resources and other factors. As of the date of filing this report, there is no material pending legal proceeding to which we are a party or to which any of our property is subject.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the Nasdaq Capital Market under the symbol “DARE.”

Holders of Common Stock

As of March 28, 2025, we had approximately 34 stockholders of record.

The number of stockholders of record is based upon the actual number of holders registered on our books at such date. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws and contractual limitations, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED.]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and the notes thereto included in Part II, Item 8 of this report. This following discussion includes forward-looking statements. See PART I "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS,” above. Forward-looking statements are not guarantees of future performance and our actual results may differ materially from those currently anticipated and from historical results depending upon a variety of factors, including, but not limited to, those discussed in Part I, Item 1A of this report under the heading “Risk Factors,” which are incorporated herein by reference.

Business Overview

We are a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority. We exist to accelerate innovation in women’s health and we believe that innovation does not have to start from scratch. With growing awareness around menopause, sexual health, and vaginal health, the conversation is shifting, but access to real, evidence-based solutions still lags behind. We continuously hear from healthcare providers, researchers, and women themselves about the urgent need for access to evidence-based treatment options. Our goal is to fulfill that need by bringing to market as soon as practicable innovative evidence-based treatment solutions that address decades of unmet needs in women’s health and enhance outcomes and convenience, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause - areas in women's health that we believe represent compelling and meaningful market opportunities. The needed medical treatment solutions we aim to bring to market will primarily be available only with a physician’s prescription – either as an FDA-approved product or as a compounded drug under Section 503B of the FDCA. We may also bring to market consumer health products that can be obtained without a physician’s prescription. As discussed in more detail below, we are taking action to utilize 503B compounding to bring our

proprietary Sildenafil Cream formulation to market, and we are targeting to make it available in the fourth quarter of 2025. See "—Recent Events—Bringing Sildenafil Cream to Market under Section 503B."

The first FDA-approved product to emerge from our portfolio is XACIATO. We achieved FDA approval of XACIATO three years after acquiring rights to the program. In 2022, we entered into an agreement with Organon, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023 and, in January 2024, Organon announced that XACIATO was available nationwide. As discussed below, to provide funding for the development of the product candidates in our pipeline, in April 2024, we entered into an agreement with XOMA whereby we sold our rights to all royalty and potential milestone payments based on net sales of XACIATO under our agreement with Organon, net of our obligations to certain third parties, until XOMA receives a specified return on its investment, after which we will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon.

Our product pipeline includes diverse programs that target unmet needs in women's health in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause, and aim to expand treatment options, enhance outcomes and improve ease of use for women. We are primarily focused on progressing the development of our existing portfolio of product candidates. However, we also explore opportunities to expand our portfolio and commercial offerings by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on women's health.

Our current portfolio includes five product candidates in advanced clinical development (Phase 2-ready to Phase 3):

- **Ovaprene®**, a hormone-free, monthly intravaginal contraceptive;
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the female genitalia on demand for the treatment of female sexual arousal disorder (FSAD);
- **DARE-HRT1**, an intravaginal ring designed to deliver combination menopausal hormone therapy, bio-identical 17β-estradiol and progesterone together, continuously over a 28-day period, for the treatment of moderate-to-severe VMS, also known as hot flashes;
- **DARE-VVA1**, a proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of GSM (formerly called VVA); and
- **DARE-HPV**, a proprietary, fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert, which we plan to develop for the treatment of genital HPV infection in women, treatment of CIN (also known as cervical dysplasia), and other HPV-related pathologies.

Our portfolio also includes six product candidates in Phase 1 clinical development or that we believe are Phase 1-ready:

- **DARE-PDM1,** a proprietary hydrogel formulation of diclofenac, a nonsteroidal anti-inflammatory drug, for vaginal administration as a treatment for primary dysmenorrhea;
- **Casea S**, an investigational biodegradable contraceptive implant designed to control release of etonogestrel for a set period of time (18-24 months) before dissolving;
- **DARE-204** and **DARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively;
- **DARE-FRT1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth.

In addition, our portfolio includes the following preclinical stage programs:

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;

- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- **DARE-PTB2**, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein.

See ITEM 1. "BUSINESS," in Part I of this report for additional information regarding our product candidates.

Our primary operations consist of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or regulatory approval. During 2025, we are also taking action to bring our proprietary Sildenafil Cream formulation to market under Section 503B of the FDCA. Until we secure additional capital to fund our operating needs, we will focus our resources primarily on advancement of Ovaprene. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 and DARE-HPV programs, but we also expect such expenses will be supported by non-dilutive funding, with respect to DARE-LARC1, through at least 2026, and with respect to DARE-HPV, through October 2026. See Note 15, "Grant Awards" to the accompanying consolidated financial statements for additional information.

As discussed below, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. Our business is subject to a number of risks common to biopharmaceutical companies (see ITEM 1A. RISK FACTORS in Part I of this report) and the process of developing and obtaining regulatory approvals for prescription drug and drug/device products in the United States and in foreign jurisdictions is inherently uncertain and requires the expenditure of substantial financial resources without any guarantee of success. The commercialization of a product and compliance with applicable laws and regulations requires the expenditure of further substantial financial resources without any guarantee of commercial success. The amount of post-approval financial resources required for commercialization and the potential revenue we may receive from sales of any product will vary significantly depending on many factors, including whether, and the extent to which, we establish our own sales and marketing capabilities and/or enter into and maintain commercial collaborations with third parties with established commercialization infrastructure.

Recent Events

Bringing Sildenafil Cream to Market under Section 503B

We are taking action to bring our proprietary Sildenafil Cream formulation to market under Section 503B of the FDCA, and we expect to begin recording revenue from sales therefrom, in the fourth quarter of 2025. See ITEM 1. “BUSINESS–503B Compounding” in Part I of this report for additional information.

Bringing our proprietary Sildenafil Cream formulation to market under Section 503B is part of our dual-path approach to bring some of our proprietary formulations to market as soon as practicable because we believe women should not have to wait for a needed solution while we continue to pursue FDA approval of our product candidates. In parallel, we will continue to pursue FDA approval of Sildenafil Cream as a treatment for FSAD. Bringing our proprietary Sildenafil Cream formulation to market via 503B compounding will not impact the regulatory process or commercial opportunity for an FDA-approved Sildenafil Cream product. Rather, if successful, 503B compounding will be a source of revenue from existing assets that is non-dilutive to our stockholders.

To bring our proprietary Sildenafil Cream formulation to market under Section 503B, among other things, we will need to successfully identify and enter into satisfactory arrangements with one or more 503B-registered outsourcing facilities, and we intend to focus our resources on provider-to-provider education about disease state and our proprietary Sildenafil Cream formulation, leveraging online resources, including web-based ordering platforms and collaborations with telehealth platforms and providers. We anticipate needing to invest no more than $1.0 million to support a 503B-registered outsourcing facility with technology-transfer activities specific to our Sildenafil Cream formulation, activate an awareness campaign, and facilitate access to our proprietary Sildenafil Cream formulation as an option for providers and women. We are targeting the second quarter of 2025 to provide an update on the strategic partnerships to achieve these objectives.

Noncompliance with Nasdaq’s Minimum Market Value of Listed Securities Requirement

On August 12, 2024, we received a letter from The Nasdaq Stock Market LLC, or Nasdaq, notifying us that we do not meet the requirement in Nasdaq Listing Rule 5550(b)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(2) requires a company listed on Nasdaq to maintain a minimum market value of listed securities of $35.0 million, which we refer to as the Minimum MVLS Rule. We were provided an initial period of 180

calendar days, or until February 10, 2025, to regain compliance with the Minimum MVLS Rule.

On February 13, 2025, Nasdaq's Listing Qualifications Department notified us that because the we did not regain compliance with the Minimum MVLS Rule by February 10, 2025, our common stock is subject to delisting from Nasdaq unless we timely requests a hearing before the Nasdaq Hearing Panel, or the Panel.

On February 20, 2025, we requested a hearing before the Panel, which request stayed the delisting of our common stock pending the decision of the Panel following the hearing and the expiration of any extension period that may be granted by the Panel. The hearing occurred on March 25, 2025. Pursuant to published Nasdaq guidance, the Panel typically issues its decision within 30 days of the hearing.

There can be no assurance that the Panel will grant us any extension period within which to regain compliance with the Minimum MVLS Rule, or if any extension period is granted, that we will regain compliance with the Minimum MVLS Rule within such extension period, or that we will be successful in otherwise maintaining the listing of our common stock on The Nasdaq Capital Market. See the risk factor titled, *If we fail to regain and maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock*, under "Risks Related to Our Securities" in ITEM 1A. *RISK FACTORS of this report*.

NICHD Performance under the CRADA for the Pivotal Phase 3 Study of Ovaprene

See ITEM 1. "BUSINESS– Our Pipeline: Clinical-Stage Programs– Ovaprene®– Pivotal Phase 3 Clinical Study" in Part I of this report for a discussion of the impact of executive orders and other actions taken by the new U.S. presidential administration in the first quarter of 2025 on the Phase 3 clinical study of Ovaprene and NICHD's ability to carry out its responsibilities under the CRADA.

Theramex Co-Development and Licensing Agreement

See ITEM 1. "BUSINESS– Strategic Agreements for Pipeline Development– Theramex Co-Development and License Agreement" in Part I of this report for a discussion of the agreement we entered into with Theramex in February 2025.

Receipt of Grant Funding Installment to Support DARE-LARC1

In December 2024, we received a payment of $2.5 million as the latest installment under a grant to advance the development of our investigational contraceptive DARE-LARC1 in nonclinical proof-of-principle studies and other IND-enabling work to allow for the submission of an IND application with the FDA, approval of which will be required to commence testing in humans. Under the terms of the grant agreement, we may receive a total of up to approximately $49.0 million to support nonclinical development of DARE-LARC1. As of the filing date of this report, we had received a cumulative total of approximately $31.8 million of such total potential amount under the grant agreement. Additional payments are conditioned on the program meeting specified development and reporting milestones. See Note 15, "Grant Awards- Other Non-Dilutive Grant Funding- 2021 DARE-LARC1 Grant Agreement" to the accompanying consolidated financial statements for additional information regarding the grant agreement.

Non-Dilutive Funding Awards for DARE-HPV

In December 2024, we received a notice of award from the National Institute of Allergy and Infectious Diseases (NIAID), a component of the NIH, that we were awarded a $1.0 million grant in support of non-clinical activities for the development of DARE-HPV for an initial project year of December 2024 through November 2025, and that an additional $1.0 million was recommended for a subsequent year, subject to the availability of funds and satisfactory progress of the project, as determined by NIAID.

In October 2024, we entered into a subaward agreement with National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell under which we are entitled to receive up to $10.0 million in milestone-based payments subject to our achievement of specified research activities and objectives relating to advancement of our DARE-HPV program, including commencement of a Phase 2 clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for the clearance of high-risk HPV infection in women, over an approximately 24-month period ending in October 2026. We anticipate that more than half of the award amount will become payable to us during the first 12 months of the performance period under the subaward agreement. To date, we have received payments totaling $2.5 million. The subaward agreement was the result of our selection as an awardee by an agency within the HHS.

Grant Agreement to Support the Ovaprene Phase 3 Study and Identification & Development of a New Non-Hormonal Contraceptive Candidate

In November 2024, we entered into a grant agreement with the Foundation, under which we were awarded a new grant of up to approximately $10.7 million to support (i) expansion of the number of study sites in the ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in low- and middle-income country settings who need or would prefer to use such a product to avoid an unplanned pregnancy. We received an initial payment under the grant agreement of approximately $5.4 million in November 2024. Additional payments are contingent upon our achievement of specified development and reporting milestones during the term of the grant agreement, which extends through October 2026. See Note 15, "Grant Awards--Other Non-Dilutive Grant Funding--2024 Contraceptive Product Candidate Grant Agreement" to the accompanying financial statements for additional information regarding the grant agreement.

Equity Line

In October 2024, we entered into a purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the purchase agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million in shares of our common stock. Such sales of our common stock to Lincoln Park, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 24-month period commencing on November 27, 2024, which we refer to as the Commencement Date.

From time to time after the Commencement Date, at our sole discretion, on any business day selected by us on which the closing sale price of our common stock is not below $0.50 per share, we may direct Lincoln Park to purchase up to 30,000 shares of our common stock (or up to 35,000 and 40,000 shares if the closing sale price of our common stock on the day on which we initiate a purchase is not below $5.00 or $7.50, respectively, subject to customary adjustments for stock splits and similar transactions) at a purchase price equal to the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the purchase and (ii) the average of the three lowest closing sale prices of our common stock during the 10-business day period immediately preceding the business day on which we initiate the purchase. However, Lincoln Park's maximum commitment in any single purchase may not exceed $500,000. In addition, we may also direct Lincoln Park to purchase other amounts of common stock as accelerated purchases and as additional accelerated purchases, subject to limits specified in the purchase agreement, at a purchase price per share calculated as specified in the purchase agreement, but in no case lower than the minimum price per share we stipulate in our notice to Lincoln Park initiating these purchases.

In addition, under applicable Nasdaq rules, we may not issue or sell to Lincoln Park under the purchase agreement more than 1,711,172 shares of our common stock, which we refer to as the Exchange Cap, unless (i) we obtain stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the equity line agreement equals or exceeds $3.59 per share (which represents the lower of (A) the official closing price per share of our common stock on Nasdaq immediately preceding the signing of the purchase agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the purchase agreement). We may also not sell shares to Lincoln Park under the purchase agreement if it would result in Lincoln

Park beneficially owning more than 4.99% of our then outstanding shares of common stock, which limitation we refer to as the beneficial ownership cap. Lincoln Park, upon written notice to us, may increase the beneficial ownership cap to up to 9.99%. Any increase in the beneficial ownership cap will not be effective until the 61st day after such written notice is delivered to us.

In connection with entering into the purchase agreement, we issued 137,614 shares of our common stock to Lincoln Park in consideration for its commitment to purchase shares thereunder.

U.S. Government Policy and Funding and Regulatory Uncertainty

There may be significant future effects on the women's health sector and the pharmaceutical and biopharmaceutical industries as a result of federal policy and regulatory changes under the new U.S. presidential administration, including in areas relating to regulatory framework and oversight, research and development funding, drug pricing reform, global trade policy and tariffs, and others. We continue to monitor these developments, which could result in new opportunities as well as challenges. The potential effects of these changes on our business could be significant. Our business strategy has included seeking non-dilutive sources of funding and collaborations to support product development, and we have received federal government grants and awards in support of several of our development programs. Our pivotal Phase 3 study of Ovaprene and our DARE-HPV program are being significantly supported by federal government funding. Our pivotal Phase 3 study of Ovaprene is being conducted, in part, under our CRADA with NICHD, and advancement of our DARE-HPV program is being supported by federal government funding under our October 2024 subaward agreement with VentureWell and a December 2024 grant award from NIAID. Our subaward agreement will automatically terminate if the prime agreement from which the federal government funding flows is terminated and may be terminated for convenience by VentureWell if the prime agreement is materially changed in a way that would materially adversely affect VentureWell financially and, if so terminated, we would be paid only for milestones achieved up to the date of termination. As discussed in ITEM 1. "BUSINESS– Our Pipeline: Clinical-Stage Programs– Ovaprene®– Pivotal Phase 3 Clinical Study" in Part I of this report, executive orders and other actions taken by the U.S. presidential administration in the first quarter of 2025 have negatively impacted the Phase 3 study and NICHD's ability to carry out its responsibilities under the CRADA, and future developments, including relating to executive orders issued in January 2025, could have a material adverse impact on the study. Given the high level of uncertainty regarding federal policy and enforcement and regulatory changes under the new U.S. presidential administration and that circumstances are rapidly evolving, including as a result of legal challenges to federal government actions, we are not able to reasonably predict the potential impact on our business at this time.

Reverse Stock Split

On July 1, 2024, we effected a 1-for-12 reverse split of our issued common stock. At the effective time of the reverse stock split, every 12 shares of our common stock was automatically reclassified and combined into one share of our common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. All common stock share and per share data presented in this report for prior periods have been retroactively adjusted to reflect the impact of the reverse stock split, without giving effect to whole shares issued in lieu of fractional shares. See Notes 2 and 9 to the accompanying consolidated financial statements for additional information.

Financial Overview

Revenue

Our revenue reflects payments earned under our license agreement with Organon to commercialize XACIATO. Pursuant to our traditional royalty purchase agreement with XOMA, from and after April 1, 2024, all of the royalties and potential milestone payments we would otherwise have the right to receive under our license agreement with Organon based on net sales of XACIATO will be paid to XOMA, net of payments made under our exclusive license agreement with third-party licensors TriLogic Pharma, LLC and MilanaPharm LLC and under our royalty interest financing agreement with UiE. Accordingly, from and after April 1, 2024, any revenue we recognize under our license agreement with Organon based on net sales of XACIATO will be payable to UiE and recognized as non-cash royalty revenue.

In the future, we may generate revenue from license fees, milestone payments, and research and development payments in connection with strategic collaborations, as well as product sales of future products, if any. Our ability to generate such revenue will depend on the extent to which clinical development of our product

candidates is successful and we or a strategic collaborator receive regulatory approvals to market such product candidates, as well as the eventual commercial success of the approved products. If we fail to complete the development of our product candidates in a timely manner, or to receive regulatory approval for such product candidates, our ability to generate future revenue and our results of operations would be materially adversely affected.

Research and Development Expenses

The majority of our operating expenses during a fiscal year are research and development, or R&D, expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. We expect our R&D expenses will continue to represent the majority of our operating expenses for at least the next twelve months. R&D expenses consist primarily of:

- direct program costs, including:
  - expenses incurred under agreements with clinical research organizations (CROs), investigative sites and other third parties that assist in the conduct of our clinical trials and nonclinical studies and conduct other R&D and regulatory affairs activities on our behalf,
  - contract manufacturing expenses, primarily for the production of materials for use in our clinical trials and nonclinical studies,
  - transaction costs related to acquisitions of companies, technologies and related intellectual property, and other assets, and
  - milestone payments due to third parties under acquisition and in-licensing arrangements based on our product candidates' achievement of R&D and regulatory milestones specified therein, and
- indirect costs, including:
  - personnel-related costs, including salaries, bonuses, benefits, payroll taxes, and stock-based compensation expenses for employees engaged in R&D functions,
  - the costs of services performed by third parties, including consulting services,
  - facilities-related costs, including rent and maintenance costs, and insurance, depreciation, supplies, and miscellaneous expenses, and
  - costs related to travel, conference participation, service contracts, information technology, dues and subscriptions.

We recognize R&D expenses as they are incurred. External expenses are recognized based on our evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the amount of services that has been performed at each reporting date. Nonrefundable payments we make prior to the receipt of goods or services to be used in R&D are recognized as an expense as the related goods are delivered or services are performed. Milestone payments to third parties under acquisition, license, and option agreements are recognized as they are incurred or when we deem their incurrence to be probable.

At any one time, we are working on multiple programs at various stages of development. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each development program on an ongoing basis based on our cash resources and in response to the results of ongoing and future clinical trials and preclinical studies, regulatory developments, and our ongoing assessments as to the commercial potential of each product candidate. We generally track direct R&D costs on a specific basis and will present direct costs for our key development programs on a program-by-program basis. We plan to present direct costs for all other programs on a consolidated basis generally by stage of development. Specifically, we will present consolidated direct costs for (a) such programs that are in (i) advanced clinical development (Phase 2-ready to Phase 3), (ii) Phase 1 clinical development or that we believe are Phase 1-ready, and (iii) preclinical stage, and (b) other development programs. We do not track indirect costs on a program-by-program basis because those costs generally are deployed across multiple development programs.

Investment in the development of and seeking regulatory approval for our clinical-stage and Phase 1-ready product candidates and the development of any other potential product candidates we may advance into and through clinical trials in the pursuit of regulatory approvals, will increase our R&D expenses. Activities associated with the foregoing will require a significant increase in investment in regulatory support, clinical supplies, inventory build-up related costs, and the payment of success-based milestones to licensors. In addition, we continue to evaluate

opportunities to acquire or in-license other product candidates and technologies, which may result in higher R&D expenses due to, among other factors, milestone payments.

Until the first commercial sale of XACIATO, we recognized contract manufacturing expenses associated with producing commercial supplies of XACIATO and costs of regulatory affairs activities related to XACIATO as R&D expenses. Following the first commercial sale of XACIATO, and during the interim period when we were the NDA holder of XACIATO and provided commercial supplies of XACIATO to Organon, those expenses were recognized as general and administrative expenses.

We recognize the Australian Research and Development Tax Incentive Program, or the Tax Incentive, as a reduction of R&D expenses (contra-R&D expense). The amounts are determined based on our eligible R&D expenditures and are non-refundable, provided that in order to qualify for the Tax Incentive the filing entity must have revenue of less than AUD $20.0 million during the tax year for which a reimbursement claim is made and cannot be controlled by an income tax exempt entity. The Tax Incentive is recognized when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured or reliably estimated.

We have received, and may in the future receive, funding through grants and other financial awards from governmental entities, private foundations and other organizations that support activities related to the development of certain of our product candidates. As we incur eligible expenses under those grants or awards, we recognize grant funding in our statements of operations as a reduction to R&D expenses (contra-R&D expense). For more information, see Note 2, "Basis of Presentation and Summary of Significant Accounting Policies – Grant Funding" to the accompanying consolidated financial statements. For the years ended December 31, 2024 and 2023, we recognized contra-research and development expense of approximately $8.8 million and $9.3 million, respectively.

Conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may not obtain regulatory approval for any product candidate on a timely or cost-effective basis, or at all. Our future R&D expenses and the probability of success of our product candidates may be affected by numerous factors, including the number, scope, rate of progress, expense, and results of our clinical trials and nonclinical R&D activities, the countries in which our clinical trials are conducted, the phase of clinical development of our product candidates, the cost and timing of manufacturing our product candidates, our ability to scale up manufacturing as needed to support later-stage clinical trials and, if approved, commercialization of our product candidates, the extent of changes in government regulation and regulatory guidance relating to development and approval of our product candidates, the timing, receipt, and terms of any clearances to conduct clinical trials and any marketing approvals from applicable regulatory authorities, competition and commercial viability of our product candidates, the extent to which we establish and maintain intellectual property rights, the extent to which we establish and maintain license, collaboration, or other arrangements. As a result, we cannot accurately determine the duration and completion costs of development projects or if, when and to what extent we will generate revenue from any products we develop.

License Fee Expenses

License fee expenses consist of up-front license fees and annual license fees due under our in-licensing arrangements.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services, commercial-readiness expenses, and milestone expenses. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs. Commercial-readiness expenses consist of consultant and advisor costs. Milestone expenses consist of amounts that become due to third parties under our in-license or other agreements under which we acquired rights to technology or other intellectual property we use in a product based on the product's achievement of commercial milestones specified therein.

Recently Issued Accounting Standards

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations and cash flows is discussed in Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

Management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements that we prepared in accordance with accounting principles generally accepted in the United States. Preparing these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

While our significant account policies are described in more detail in Note 2 to our consolidated financial statements included herein, we believe that the following accounting policies are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

- Revenue Recognition;
- Stock-Based Compensation;
- Sale of Future Payments;
- Grant Funding; and
- Clinical Trial Expense Accruals.

Revenue Recognition

Under ASC Topic 606, or ASC 606, we recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, we perform five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy our performance obligations. At contract inception, we assess the goods or services agreed upon within each contract, assess whether each good or service is distinct, and determines those that are performance obligations. We then recognize as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, we develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Collaboration Revenues. We enter into collaboration and licensing agreements under which we out-license certain rights to our products or product candidates to third parties. The terms of these arrangements typically include payment of one or more of the following to us: non-refundable, up-front license fees; development, regulatory and/or commercial milestone payments; and royalties on net sales of licensed products. To date, we have not recognized any collaboration revenues.

License Fee Revenue. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in a contract, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. To date, we have recognized $11.0 million in license fee revenue, all from payments received under our license agreement with Organon to commercialize XACIATO.

Milestones. At the inception of each arrangement in which we are a licensor and that includes developmental, regulatory or commercial milestones, we evaluate whether achieving the milestones is considered probable and

estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments not within our control, such as where achievement of the specified milestone depends on activities of a third party or regulatory approval, are not considered probable of being achieved until the specified milestone occurs. To date, we have recognized $1.8 million of milestone revenue, which represents the $1.8 million milestone payment we received under our license agreement with Organon in connection with the first commercial sale of XACIATO.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have recognized approximately $18,000 of royalty revenue.

Product Supply. Arrangements that include a promise for future supply of product for commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. We evaluate whether we are the principal or agent in the arrangement based on the degree we control the specified product at any time before transfer to the customer. If we are in the capacity of a principal, revenues are recognized on a gross basis. If we are in the capacity of an agent, revenues are recognized on a net basis. To date, we have recognized approximately $205,000 in revenue (and $201,000 in other expense attributed to the cost of revenue) associated with our XACIATO product supply arrangement, which is recorded in other income in our consolidated statements of operations and comprehensive loss. In connection with the transfer of the NDA for XACIATO to Organon in December 2023, that arrangement was terminated and we will not recognize product supply revenue associated with that arrangement in the future.

Stock-Based Compensation

The compensation cost for all stock-based awards is measured at the grant date, based on the fair value of the award (determined using a Black-Scholes option pricing model), and is recognized as an expense over the requisite service period (generally the vesting period of the award). Determining the fair value of stock-based awards at the grant date requires significant estimates and judgments, including estimating the market price volatility of our common stock, future stock option exercise behavior and requisite service periods. Due to our limited history of stock option exercises, we applied the simplified method prescribed by SEC Staff Accounting Bulletin 110, Share-Based Payment: Certain Assumptions Used in Valuation Methods - Expected Term, to estimate expected life.

Stock options or stock awards with performance conditions issued to non-employees who are not directors are measured on the grant date and recognized when the performance is complete. Refer to Note 10 to our consolidated financial statements included in this report for more information.

Sale of Future Payments

On April 29, 2024, we entered into and closed a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (US) LLC ("XOMA") pursuant to which we sold our right, title and interest in the following to XOMA (i) all future net royalty and potential net milestone payments we would otherwise receive from Organon based on net sales of XACIATO, (ii) a portion of future net sales of Ovaprene and a portion of a potential future milestone payment we may receive under our license agreement with Bayer related to Ovaprene, and (iii) a portion of future net sales of Sildenafil Cream. We received $22.0 million from XOMA in connection with entering into the royalty purchase agreements. Under the terms of the royalty purchase agreements, if XOMA receives total payments under the royalty purchase agreements equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to us for each successive $22.0 million XOMA receives under the royalty purchase agreements. If we earn any such payments, they will be accounted for as variable consideration under ASC 606, *Revenue Recognition,* and will be recorded as income when such payments are received.

We evaluated the expected cash flows to XOMA from royalties and milestone payments expected to be earned on XACIATO, Ovaprene and Sildenafil Cream over the period that we expect it will take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements, and determined to allocate the $22.0 million we received from XOMA in connection with entering into the royalty purchase agreements, net of transaction costs of approximately $1.6 million, to the traditional royalty purchase agreement for XACIATO, and none of it to the synthetic royalty purchase agreement for Ovaprene and Sildenafil Cream. Until such time that we are certain of commercialization, the cash flows to XOMA from royalties and milestone payments expected to be earned on Ovaprene and Sildenafil Cream are expected to be de minimis over the period that we expect it will take for XOMA to

receive total payments of $88.0 million under the royalty purchase agreements because, unlike XACIATO, Ovaprene and Sildenafil Cream are not commercial assets at this time.

We determined that the traditional royalty purchase agreement represents a complete sale of a nonfinancial asset (our right, title and interest in and to future payments related to commercial sales of XACIATO) for which XOMA bears all benefit and for which we have no obligations or involvement going forward, and therefore should be accounted for within the scope of Accounting Standards Codification ("*ASC") 610-20, Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets*. The $22.0 million net of transaction costs of approximately $1.6 million was recorded as other income on our consolidated statements of operations and comprehensive loss.

Grant Funding

We receive certain research and development funding under grants issued by the U.S. government and a not-for-profit foundation. In accordance with a policy we adopted in 2018, we recognize grant funding in the statements of operations as a reduction to R&D expense, or contra R&D, as the related costs are incurred to meet those obligations over the grant period. Grant funding payments received in advance of research and development expenses incurred are recorded as deferred grant funding liability in our consolidated balance sheets. For the years ended December 31, 2024 and December 31, 2023, there were no material adjustments to our prior period estimates of grant funded research and development expenses. Refer to Note 15 to our consolidated financial statements included in this report for more information.

Clinical Trial Expense Accruals

We estimate expenses resulting from our obligations under contracts with vendors, CROs and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided.

We record clinical trial expenses in the period in which services are performed and efforts are expended. We accrue for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We estimate accruals through financial models taking into account discussion with applicable personnel and outside service providers as to the progress of trials. During the course of a clinical trial, we may adjust our clinical accruals if actual results differ from our estimates. We estimate accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are dependent upon accurate reporting by CROs and other third-party vendors. Although we do not expect our estimates to differ materially from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2024 and December 31, 2023 there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

Results of Operations

Comparison of the Years ended December 31, 2024 and 2023

The following table summarizes our consolidated results of operations for the years ended December 31, 2024 and 2023, and the change in the applicable line item in terms of dollars and percentage:

	Years Ended December 31,		Change	
	2024	2023	$	%
Revenue				
License fee revenue	$ —	$ 1,000,000	$ (1,000,000)	(100)%
Milestone revenue	—	1,800,000	(1,800,000)	(100)%
Royalty revenue	9,784	7,885	1,899	24 %
Total revenue	9,784	2,807,885	(2,798,101)	(100)%
Operating expenses				
General and administrative expenses	$ 9,156,061	$ 12,109,691	$ (2,953,630)	(24)%
Research and development expenses	14,205,208	21,538,074	(7,332,866)	(34)%
License fee expenses	100,000	100,000	—	— %
Total operating expenses	23,461,269	33,747,765	(10,286,496)	(30)%
Loss from operations	(23,451,485)	(30,939,880)	7,488,395	24 %
Other income (expense)				
Sale of royalty and milestone rights, net	20,379,376	—	20,379,376	100 %
Other income (expense), net	(981,490)	778,489	(1,759,979)	(226)%
Net loss	$ (4,053,599)	$ (30,161,391)	$ 26,107,792	(87)%

Revenues

Revenues for the years ended December 31, 2024 and 2023 related to our license agreement with Organon to commercialize XACIATO. For 2023, we recognized $1.0 million in license fee revenue upon execution of the amendment to the license agreement in July 2023, $1.8 million in milestone revenue in connection with the first commercial sale of XACIATO, and approximately $7,900 in royalties from net sales of XACIATO in the fourth quarter.

General and administrative expenses

The decrease of approximately $3.0 million in general and administrative expenses from 2023 to 2024 was primarily attributable to decreases in (i) commercial-readiness expenses of approximately $1.6 million, (ii) personnel costs of approximately $0.6 million due to reduced headcount, (iii) stock-based compensation expense of approximately $0.3 million, (iv) a one-time fraud loss in the first quarter of 2023 of approximately $0.2 million, net of proceeds we received under an insurance policy, related to criminal fraud commonly referred to as "business email compromise fraud" to which we were subject, and (v) professional services expenses of approximately $0.2 million.

Research and development expenses

The following table summarizes our R&D expenses for the periods indicated, together with the changes in those items in terms of dollars and percentage:

	Years Ended December 31,		Change	
	2024	2023	$	%
Direct program costs:				
Ovaprene [1]	$ 8,518,495	$ 3,762,611	$ 4,755,884	126 %
Sildenafil Cream, 3.6%	2,361,052	7,746,264	(5,385,212)	(70)%
Other advanced clinical stage programs	1,321,888	3,498,955	(2,177,067)	(62)%
Phase 1 and Phase 1-ready clinical stage programs [1]	761,721	2,912,857	(2,151,136)	(74)%
Preclinical stage programs [1]	4,233,762	7,432,439	(3,198,677)	(43)%
Other development programs	27,542	189,706	(162,164)	(85)%
Contra R&D expenses [2]	(7,685,533)	(8,965,347)	1,279,814	(14)%
Total direct program costs	9,538,927	16,577,485	(7,038,558)	(42)%
Indirect costs:				
Personnel-related (including stock compensation)	5,611,057	5,566,016	45,041	1 %
Outside services (including consulting)	543	38,114	(37,571)	(99)%
Facilities-related (including depreciation)	78,168	86,239	(8,071)	(9)%
Other indirect R&D costs	176,061	259,936	(83,875)	(32)%
Contra R&D expenses	(1,199,548)	(989,716)	(209,832)	21 %
Total indirect R&D costs	4,666,281	4,960,589	(294,308)	(6)%
Total R&D expenses	$ 14,205,208	$ 21,538,074	$ (7,332,866)	(34)%

(1) The applicable program(s) receive grant funding and/or the Tax Incentive. The amount of R&D expense for the period indicated is shown on a gross basis (i.e., without deducting the amount of contra R&D expense for the applicable program(s). See footnote (2) below.

(2) These contra R&D expenses were recognized as follows for the years ended December 31, 2024 and 2023: (a) Ovaprene, $0.2 million, and $0, respectively; (b) Other advanced clinical stage programs, $0 and $0.1 million, respectively, (c) Phase 1 and Phase 1-ready clinical stage programs, $1.3 million and $0.9 million, respectively; and (d) Preclinical stage programs, $6.2 million and $7.9 million, respectively.

The decrease of approximately $7.3 million in R&D expenses from 2023 to 2024 was primarily attributable to a decrease in costs related to development activities for Sildenafil Cream as a result of the completion of the Phase 2b RESPOND clinical study completed in June 2023, partially offset by increases in costs related to our ongoing pivotal Phase 3 clinical trial of Ovaprene and manufacturing and regulatory affairs activities for Ovaprene. Contra-R&D expenses for the years ended December 31, 2024 and 2023 primarily offset direct program costs for DARE-LARC1, one of our preclinical stage programs.

License fee expenses

For each of the years ended December 31, 2024 and December 31, 2023 we accrued or paid $100,000 of the annual license maintenance fee payable under our license agreement related to DARE-HRT1. For further discussion of this annual license maintenance fee, see Note 3 "Strategic Agreements—Strategic Agreements for Pipeline Development" to the accompanying consolidated financial statements.

Other income (expense)

Sale of royalty and milestone rights, net

The $20.4 million of other net income for 2024 represents the $22.0 million payment to us in April 2024 under the Royalty Purchase Agreements, net of approximately $1.6 million in transaction costs.

Other income (expense), net

The decrease of $1.8 million in other income (expense) for 2024 as compared to 2023 was primarily due to a loss on the disposal of a fixed asset of $0.6 million, interest expense related to the Royalty Interest Agreement in 2024 of approximately $0.8 million, and decreased interest earned on cash balances in 2024.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

At December 31, 2024, we had an accumulated deficit of approximately $175.3 million, cash and cash equivalents of approximately $15.7 million, and a working capital deficit of approximately $3.2 million. We will need additional capital to fund our operating needs into the third quarter of 2025 and to meet our current obligations as they become due. All of our cash and cash equivalents at December 31, 2024 represented funds received under grant agreements that generally may be applied solely toward direct costs of carrying out the respective projects under those grant agreements.

We prepared the accompanying consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. We have a history of losses from operations and we expect significant losses from operations, net losses, and negative cash flows from operations for at least the next several years as we continue to develop and seek to bring to market our product candidates. We are dependent on securing substantial additional capital from one or more third-party sources to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

We are in ongoing discussions with potential third-party sources of additional capital, and we will continue to evaluate and may pursue a variety of capital raising options, including sales of equity (including sales of our common stock under our equity line arrangement and in ATM offerings (see "—Capital Resources," below)), debt financings, government or other grant funding, collaborations, structured financings, and strategic alliances or other similar types of arrangements. However, our ability to raise additional capital will depend on a variety of factors, many aspects of which are not entirely within our control, and there can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders. Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights in our technologies or product candidates and their future revenue streams. See the risk factors under "Risks Related to Our Financial Position and Capital Needs" in ITEM 1A. RISK FACTORS of this report.

If we cannot raise capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our product candidate programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. For example, in recent years, due to our limited capital resources, we have focused our resources primarily on the advancement of Ovaprene and Sildenafil Cream, unless a program has been supported by grant or other non-dilutive funding, and we have delayed R&D activities for other programs. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

A majority of our operating expenses during a fiscal year are R&D expenses. Our R&D expenses for 2025, until we secure additional capital to fund our operating needs, will be primarily associated with our ongoing pivotal Phase 3 clinical study of Ovaprene. However, we plan to continue to advance preclinical development of DARE-LARC1, the costs of which are being supported by grant funding, and, with the support of funding under our October 2024 subaward agreement and the December 2024 NIAID grant award, to advance development of DARE-HPV toward a Phase 2 clinical study. Assuming we are able to raise the necessary capital to continue our operations, we anticipate our R&D expenses and our general and administrative expenses for 2025 will be similar to the amount of such expenses for 2024.

We expect our operating expenses for the foreseeable future to continue to be R&D expenses and general and administrative expenses consistent with the nature of such expenses described above under "Financial Overview." Our future expenses could also include significant costs related to commercialization of our product candidates, if approved, depending on the type, nature and terms of commercial collaborations we establish, and in particular, if we determine to engage in commercialization activities directly as opposed to through a third-party collaborator. Our future capital requirements are difficult to predict because they will depend on many factors that are highly variable and difficult to predict, including, but not limited to, those discussed under "Risks Related to Our Financial Position and Capital Needs" in ITEM 1A. RISK FACTORS of this report. We cannot accurately determine the

duration and completion costs of our development programs, or if, when and to what extent we will generate revenue from any products we develop.

Capital Resources

Historically, the cash used to fund our operations has come from a variety of sources and predominantly from sales of shares of our common stock. We have also received a significant amount of cash through non-dilutive grants, strategic collaborations and royalty monetization transactions.

We have a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, to sell shares of our common stock from time to time through an ATM offering under which Stifel acts as our agent. During 2024, we sold 109,655 shares of our common stock under the sales agreement for net proceeds of approximately $0.5 million. Shares of our common stock sold under the sales agreement will be offered and sold under our shelf registration statement on Form S-3 (File No. 333-278380), declared effective by the SEC on May 10, 2024, the base prospectus included therein and the prospectus supplement thereto dated May 10, 2024 relating to the offering of up to $18.1 million of shares of our common stock, and any subsequent prospectus supplement related to the offering of shares of our common stock under the sales agreement.

We have a purchase agreement with Lincoln Park under which, subject to the conditions thereof, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million in shares of our common stock. Such sales of our common stock to Lincoln Park, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 24-month period commencing on November 27, 2024. We did not sell any shares of our common stock under this purchase agreement during 2024. See “—Recent Events—Equity Line,” above.

As discussed above, we are seeking to bring our proprietary Sildenafil Cream formulation to market under Section 503B of the FDCA, and we expect to begin recording revenue from sales therefrom, in the fourth quarter of 2025, however, we do not expect the amount of such revenue, if any, to be material during 2025.

Our royalty purchase agreements with XOMA may be a source of future capital; however, whether we receive any future payments from XOMA will depend on whether XOMA first receives total payments under those agreements equal to an amount that exceeds $88.0 million, which may not occur and will depend, in part, on the commercial success of XACIATO, which is outside of our control.

Our license agreement with Bayer regarding the further development and commercialization of Ovaprene in the U.S., if approved, may be a future source of capital; however, whether we receive any future payments from Bayer will depend on whether Bayer, in its sole discretion, exercises its right to make the license effective by paying us $20.0 million after we complete the ongoing pivotal Phase 3 clinical study of Ovaprene, which we do not expect to be completed in 2025. In addition, a portion of that potential $20.0 million payment from Bayer would be payable to XOMA as discussed under “—Contractual Obligations and Other Commitments—Royalty Purchase Agreements with XOMA,” below.

Deferred Grant Funding

We have received substantial funding under grant agreements with the Foundation, and we generally receive grant funds before we incur the eligible expenses. Under the terms of such grant agreements, the funds we receive may be applied solely toward direct costs of carrying out the respective projects under those grant agreements, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. Funds received that have not been spent are recorded both as cash and cash equivalents and as a deferred grant funding liability in our consolidated balance sheets. Funds received that have been spent but not yet expensed in accordance with GAAP are also recorded as part deferred grant funding liability in our consolidated balance sheets. As of December 31, 2024, our deferred grant funding liability was approximately $16.6 million, substantially all of which consisted of unspent funds for the DARE-LARC1 program and the Ovaprene Phase 3 clinical study. For more information about these grant agreements, see Note 2, "Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding," and Note 15, "Grant Awards-Other Non-Dilutive Grant Funding" to the accompanying consolidated financial statements.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Years Ended December 31,	
	2024	2023
Net cash provided by (used in) operating activities	$ 5,394,247	$ (38,856,654)
Net cash used in investing activities	(573,046)	(629,430)
Net cash provided by financing activities	433,830	15,637,120
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(67,913)	(9,585)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 5,187,119	$ (23,858,549)

Net cash used in operating activities

Cash used in operating activities during the year ended December 31, 2024 included the net loss of $4.1 million, decreased by non-cash stock-based compensation expense of approximately $2.2 million. Components providing operating cash were a decrease in prepaid expenses of approximately $3.6 million, an increase in deferred grant funding of approximately $2.8 million, a decrease in other receivables of approximately $0.7 million, an increase in interest payable of approximately $0.5 million related to the Royalty Interest Financing Agreement, an increase in accrued expenses of $0.2 million, and a decrease in deposits of $0.4 million. Components reducing operating cash were a decrease in accounts payable of approximately $1.9 million and a decrease in other non-current assets of approximately $34,000.

Cash used in operating activities during the year ended December 31, 2023 included the net loss of $30.2 million, decreased by non-cash stock-based compensation expense of approximately $2.5 million. Components providing operating cash were an increase in accounts payable of approximately $1.4 million, a decrease in other receivables of approximately $0.8 million, and a decrease in prepaid expenses of approximately $0.5 million. Components reducing operating cash were a decrease in accrued expenses of approximately $8.3 million, a decrease in deferred grant funding of approximately $4.6 million, an increase in deposits of $1.2 million primarily related to deposits paid for the construction of capital equipment, and a decrease in other non-current assets of approximately $10,000.

Net cash used in investing activities

Net cash used in investing activities during the years ended December 31, 2024 and December 31, 2023 was related to purchases of property and equipment of approximately $573,000 and $629,000, respectively.

Net cash provided by financing activities

Net cash provided by financing activities during the year ended December 31, 2024 was approximately $0.4 million and primarily consisted of proceeds from (i) the sale of our common stock under our ATM sales agreement and (ii) the financing of certain director and officer and other liability insurance premiums, partially offset by payments on the insurance financing payable.

Net cash provided by financing activities during the year ended December 31, 2023 was approximately $15.6 million and consisted of proceeds from (i) the sale of our common stock and warrants in the registered direct offering completed in September 2023 of approximately $7.0 million, (ii) the sale of future royalties of approximately $4.7 million, net, (iii) the sales of our common stock under our ATM sales agreement of approximately $2.3 million, net, (iv) the exercise of warrants of approximately $1.3 million, and (v) the financing of certain director and officer and other liability insurance premiums of approximately $0.6 million net of payments made of approximately $0.3 million.

Contractual Obligations and Other Commitments

License and Royalty Agreements

We have assembled our product pipeline primarily through acquisitions, in-license agreements, and other collaborations. We agreed to make royalty and milestone payments, and in some cases annual license fee payments, under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream and under other agreements related to our other clinical and preclinical candidates. The amount and timing of most of these payments are difficult to predict because the timing of milestone payments for pre-commercial programs generally depends on the progress of and success in development of a particular program, which is subject to many risks and uncertainties as discussed elsewhere in this report and difficult to predict, and the timing and amount of royalty and milestone payments related to commercial products generally depends on their commercial success, which may, as it is with XACIATO, be outside of our control. During 2025, based on our current expectations regarding the progress of development of our product candidates and sales of XACIATO, we expect approximately $0.1 million of such payments to upstream licensors to become payable. With respect to our license agreement relating to XACIATO, royalties payable by us to upstream licensors will be funded by royalty payments made by our licensee, Organon. For further discussion of these potential payments, see Note 3 "Strategic Agreements—Strategic Agreements for Pipeline Development" to the accompanying consolidated financial statements.

Grant Agreements

For information regarding our grant agreements with the Foundation, see "--Deferred Grant Funding," above, Note 2, "Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding" and Note 15, "Grant Awards-Other Non-Dilutive Grant Funding" to the accompanying consolidated financial statements.

Royalty Purchase Agreements with XOMA

In April 2024, we entered into a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (which, together, we refer to as the Royalty Purchase Agreements) pursuant to which we sold our right, title and interest in the following to XOMA: (a) all of the royalties and potential milestone payments we would otherwise have the right to receive from and after April 1, 2024 under our exclusive license agreement with Organon based on net sales of XACIATO, net of our obligations to upstream licensors and UiE (such net amount we refer to as the Purchased Receivables); (b) a portion of a potential future $20.0 million payment from Bayer under our license agreement relating to Ovaprene and a portion of future net sales of Ovaprene; and (c) a portion of future net sales of Sildenafil Cream (such amounts described in the foregoing clauses (b) and (c) we collectively refer to as the Revenue Participation Right). We received $22.0 million from XOMA in connection with entering into the Royalty Purchase Agreements. If XOMA receives total payments equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to us for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements.

Pursuant to the traditional royalty purchase agreement, XOMA, at its sole cost and discretion, may repay in full and retire all of our payment obligations to UiE under our royalty interest financing agreement with UiE. If XOMA does so, no further amounts in respect of that agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive. We cannot elect to receive any additional funding from UiE under our royalty interest financing agreement with UiE without XOMA's prior written consent.

In connection with the synthetic royalty purchase agreement, we granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream. The Royalty Purchase Agreements include covenants that limit or restrict our ability to incur indebtedness or liens related to the Purchased Receivables, the Revenue Participation Right, and certain product assets related to Ovaprene and Sildenafil Cream (except pursuant to a suitable intercreditor agreement).

For more information regarding our contractual obligations to XOMA, see ITEM 1. “BUSINESS— Royalty Monetization Transactions— Traditional and Synthetic Royalty Purchase Agreements with XOMA” in Part I of this report and Note 13 “Royalty Purchase Agreements” to the accompanying consolidated financial statements.

Royalty Interest Financing Agreement

In December 2023, we entered into a royalty interest financing agreement with UiE pursuant to which we sold an interest in the royalty and milestone payments we are entitled to receive in respect of net sales of XACIATO under our license agreement with Organon and received a payment of $5.0 million from UiE. We have not elected to receive

any of the up to $7.0 million in potential additional payments from UiE under the agreement, and we cannot do so without XOMA's prior written consent. In exchange for any payments to us from UiE under the agreement, we agreed to make payments to UiE out of royalty and milestone payments earned on net sales of XACIATO from Organon, net of our obligations to upstream licensors, until UiE receives a specified return on its investment. As described above, XOMA, at its sole cost and discretion, may repay in full and retire all of our payment obligations to UiE under the royalty interest financing agreement.

For more information regarding our contractual obligations to UiE, see ITEM 1. "BUSINESS— Royalty Monetization Transactions— Royalty Interest Financing Agreement" in Part I of this report and Note 12 "Royalty Interest Financing" to the accompanying consolidated financial statements.

Other Contractual Obligations

We enter into contracts in the normal course of business with various third parties for research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and we do not believe that our non-cancelable obligations under these agreements are material.

For descriptions of additional contractual obligations and commitments, see Note 14 "Commitments and Contingencies" to the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements required to be included in this Item 8 are set forth in a separate section of this report commencing on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on an evaluation, performed under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of our disclosure controls and procedures, our principal executive and financial officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of December 31, 2024 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15(f) of the Exchange Act). Our internal control over financial reporting

is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2024 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States.

Under SEC rules, because we are a non-accelerated filer, we are not required to provide an auditor attestation report on internal control over financial reporting, nor did we engage our independent registered public accounting firm to perform an audit of our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

(a) None.

(b) During the period from October 1, 2024 to December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in the Company's 2025 Proxy Statement and is incorporated in this report by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the Company's 2025 Proxy Statement and is incorporated in this report by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be included in the Company's 2025 Proxy Statement and is incorporated in this report by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in the Company's 2025 Proxy Statement and is incorporated in this report by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the Company's 2025 Proxy Statement and is incorporated in this report by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this annual report on Form 10-K:

(1) Financial Statements

See “Index to Consolidated Financial Statements” on page F-1.

(2) Financial Statement Schedules

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto included in this report.

(3) Exhibits

Exhibits not filed or furnished herewith are incorporated by reference to exhibits previously filed with the SEC, as reflected in the table below. We will furnish a copy of any exhibit to stockholders, without charge upon written request to Daré Bioscience, Inc., 3655 Nobel Drive, Suite 260, San Diego, CA 92122, or by calling 858-926-7655.

		Incorporated by Reference				
Exhibit Number	**Description of Exhibit**	**Form**	**File No.**	**Filing Date**	**Exhibit No.**	**Filed Herewith**
PLANS OF ACQUISITION						
2.1§ Δ	Agreement and Plan of Merger, dated as of April 30, 2018, by and among Daré Bioscience, Inc., Daré Merger Sub, Inc., Pear Tree Pharmaceuticals, Inc., and Fred Mermelstein and Stephen C. Rocamboli, as Holders' Representatives	10-Q	001-36395	8/13/2018	10.10	
2.2+	Agreement and Plan of Merger, dated November 10, 2019, Dare Bioscience, Inc., MC Merger Sub, Inc., Microchips Biotech, Inc., and Shareholder Representative Services LLC, as the stockholders' representative	8-K	001-36395	11/12/2019	2.1	
ARTICLES OF INCORPORATION AND BYLAWS						
3.1(a)	Restated Certificate of Incorporation, as amended to date	10-Q	001-36395	08/12/2024	3.1	
3.1(b)	Certificate of Correction of the Certificate of Amendment of Restated Certificate of Incorporation dated June 21, 2024	8-K	001-36395	06/27/2024	3.2	
3.2	Third Amended and Restated By-Laws (as amended through January 24, 2023)	10-Q	001-36395	5/14/2024	3.1	
INSTRUMENTS DEFINING RIGHTS OF SECURITY HOLDERS						
4.1	Specimen stock certificate evidencing the shares of common stock	10-K	001-36395	03/28/2018	4.1	

4.2	Warrant Agreement to purchase shares of common stock of the registrant with Aquilo Partners, L.P., entered into as of October 16, 2016.	10-K	001-36395	03/31/2022	4.2
4.3	Form of common stock purchase warrants issued on September 1, 2023	8-K	0001-36395	08/30/2023	4.1
4.4	Form of common stock purchase warrants issued on December 21, 2023	10-K	001-36395	03/28/2024	4.4
4.5	Description of securities of the registrant	10-K	001-36395	03/27/2020	4.6
COMMERCIAL AGREEMENTS					
10.1(a)+	Exclusive License Agreement dated March 31, 2022 between Organon International GmbH and Dare Bioscience, Inc., effective as of June 30, 2022	10-Q	001-36395	05/12/2022	10.1
10.1(b)+	First Amendment to License Agreement by and between Organon International GmbH and Dare Bioscience, Inc. entered into as of July 4, 2023	10-Q	001-36395	11/09/2023	10.2
10.2+	Consent, Waiver and Stand-By License Agreement, dated March 30, 2022, by and among TriLogic Pharma, LLC, and MilanaPharm LLC, Dare Bioscience, Inc., and Organon International GmbH.	10-Q	001-36395	05/12/2022	10.2
10.3Δ	License and Collaboration Agreement dated February 11, 2018 between Daré Bioscience, Inc., Strategic Science and Technologies-D, LLC and Strategic Science Technologies, LLC	10-K/A	001-36395	04/30/2018	10.1
10.4Δ	License Agreement dated March 19, 2017, between Daré Bioscience Operations, Inc. and ADVA-Tec, Inc.	10-Q	001-36395	11/13/2017	10.1
10.5Δ	Exclusive License Agreement made as April 24, 2018 by and between Catalent JNP, Inc. (fka Juniper Pharmaceuticals, Inc.), and Daré Bioscience, Inc.	10-Q	001-36395	8/13/2018	10.1
10.6(a)Δ	Amended and Restated Exclusive License Agreement for Atrophic Vaginitis Technology, effective as of July 14, 2006, dated August 15, 2007, by and between Fred Mermelstein, Ph.D., and Janet Chollet, M.D., and Pear Tree Women's Health Care, Inc.	10-Q	001-36395	8/13/2018	10.5

10.6(b)Δ	Amendment No. 1 to the Amended and Restated Exclusive License Agreement, dated as of October 10, 2007, by and among Fred Mermelstein, Ph.D. and Janet Chollet, M.D., and Pear Tree Pharmaceuticals, Inc.	10-Q	001-36395	8/13/2018	10.6
10.6(c)Δ	Amendment No. 2 to the Amended and Restated Exclusive License Agreement, dated as of February 13, 2017, by and among Fred Mermelstein, Ph.D., and Janet Chollet, M.D., Pear Tree Pharmaceuticals, Inc. and Bernadette Klamerus	10-Q	001-36395	8/13/2018	10.7
10.6(d)+	Amendment No. 3 to the Amended and Restated Exclusive License Agreement, effective as of February 13, 2017, by and among Fred Mermelstein, Ph.D., and Janet Chollet, M.D., Pear Tree Pharmaceuticals, Inc. and Bernadette Klamerus	10-K	001-36395	3/30/2023	10.6(d)
10.6(e)Δ	Exclusive License Agreement, dated as of February 13, 2017, by and between GYN Holdings, Inc., a wholly-owned subsidiary of Pear Tree Pharmaceuticals, Inc. and Bernadette Klamerus	10-Q	001-36395	8/13/2018	10.8
10.6(f)Δ	Exclusive License Agreement, effective as of September 15, 2017, by and between Fred Mermelstein, Ph.D., Janet Chollet, M.D., Pear Tree Pharmaceuticals, Inc., and Stephen C. Rocamboli	10-Q	001-36395	8/13/2018	10.9
10.7(a)Δ	Assignment Agreement by and between Daré Bioscience, Inc. and Hammock Pharmaceuticals, Inc. effective as of December 5, 2018	10-K	001-36395	04/01/2019	10.10(a)
10.7(b)Δ	First Amendment to the License Agreement effective as of December 5, 2018 by and among Daré Bioscience, Inc., TriLogic Pharma, LLC and MilanaPharm LLC	10-K	001-36395	04/01/2019	10.10(b)
10.7(c)	Amendment No. 1 to Assignment Agreement entered into as of December 4, 2019 between Daré Bioscience, Inc. and Hammock Pharmaceuticals, Inc.	10-K	001-36395	03/27/2020	10.10(c)
10.7(d)	Amendment No. 2 to the License Agreement entered into as of December 3, 2019 between Daré Bioscience, Inc., TriLogic Pharma, LLC and MilanaPharm LLC	10-K	001-36395	03/27/2020	10.10(d)

10.7(e)	Amendment to License Agreement effective as of September 21, 2021 by and among Daré Bioscience, Inc., TriLogic Pharma, LLC and MilanaPharm LLC	10-Q	001-36395	11/10/2021	10.1	
10.8+	License Agreement dated as of January 10, 2020 between Bayer HealthCare LLC and Daré Bioscience, Inc.	10-K	001-36395	03/27/2020	10.16	
10.9+	Cooperative Research and Development Agreement entered into as of July 8, 2021 between Daré Bioscience, Inc. and the Eunice Kennedy Shriver National Institutes of Child Health and Human Development Institute	10-Q	001-36395	11/10/2021	10.2	
10.10+	License Agreement dated as of August 12, 2023 between Douglas Pharmaceuticals Limited and Daré Bioscience, Inc.					X
10.11+	Grant Agreement between Daré Bioscience, Inc. and the Bill & Melinda Gates Foundation effective as of June 30, 2021, as amended to date					X
10.12+	Grant Agreement between Daré Bioscience, Inc. and the Bill & Melinda Gates Foundation effective as of November 11, 2024, as amended to date					X
10.13+	Subaward Agreement between the Consortium Management Firm, National Collegiate Inventors and Innovators Alliance, Inc. d/b/a/ VentureWell and Daré Bioscience, Inc., effective as of October 12, 2024					X
10.14	Royalty Interest Financing Agreement entered into as of December 21, 2023 between Dare Bioscience, Inc. and United in Endeavor, LLC	10-K	001-36395	03/28/2024	10.12	
10.15	Purchase Agreement, dated October 21, 2024, by and between Daré Bioscience, Inc. and Lincoln Park Capital Fund, LLC	8-K	001-36395	10/21/2024	10.1	
10.16	Registration Rights Agreement, dated October 21, 2024, by and between Daré Bioscience, Inc. and Lincoln Park Capital Fund, LLC	8-K	001-36395	10/21/2024	10.2	

10.17+	Traditional Royalty Purchase Agreement between Daré Bioscience, Inc. and XOMA (US) LLC, dated as of April 29, 2024	10-Q	001-36395	08/12/2024	10.1
10.18+	Synthetic Royalty Purchase Agreement between Daré Bioscience, Inc. and XOMA (US) LLC, dated as of April 29, 2024	10-Q	001-36395	08/12/2024	10.2
MANAGEMENT CONTRACTS AND COMPENSATORY PLANS					
10.13(a)*	Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	8-K	001-36395	7/12/2018	10.1
10.13(b)*	Form of Incentive Stock Option Agreement for grants under the Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	10-Q	001-36395	8/13/2018	10.3
10.13(c)*	Form of Nonstatutory Stock Option Agreement for grants under the Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	10-Q	001-36395	8/13/2018	10.4
10.14*	2014 Employee Stock Purchase Plan	S-1/A	333-194442	3/31/2014	10.26
10.15(a)*	Daré Bioscience, Inc. 2022 Stock Incentive Plan	10-Q	001-36395	8/12/2024	10.7
10.15(b)*	Form of Incentive Stock Option Agreement for Grants under the Daré Bioscience, Inc. 2022 Stock Incentive Plan	8-K	001-36395	6/24/2022	10.1(b)
10.15(c)*	Form of Nonstatutory Stock Option Agreement for Grants under the Daré Bioscience, Inc. 2022 Stock Incentive Plan	8-K	001-36395	6/24/2022	10.2(c)
10.16*	Daré Bioscience, Inc. Performance Bonus Plan, as amended	10-Q	001-36395	11/9/2023	10.3
10.17*	Form of indemnification agreement between the registrant and each of its executive officers and directors	S-1	333-194442	03/10/2014	10.16
10.18*	Amended and Restated Non-Employee Director Compensation Policy (as amended on April 2024)	10-Q	001-36395	8/12/2024	10.4
10.19(a)*	Employment Agreement by and between Daré Bioscience, Inc. and Sabrina Martucci Johnson dated as of August 15, 2017	8-K	001-36395	08/18/2017	10.1

10.19(b)*	Amendment No. 1 to Employment Agreement between Daré Bioscience, Inc. and Sabrina Martucci Johnson dated as of March 9, 2020	10-Q	001-36395	05/14/2020	10.13(b)	
10.19(c)*	Amendment No. 2 to Employment Agreement between Daré Bioscience, Inc. and Sabrina Martucci Johnson, dated as of May 20, 2024	10-Q	001-36395	08/12/2024	10.5	
10.20(a)*	Employment Agreement by and between Daré Bioscience, Inc. and Lisa Walters-Hoffert dated as of August 15, 2017	8-K	001-36395	08/18/2017	10.2	
10.20(b)*	Amendment No. 1 to Employment Agreement between Daré Bioscience, Inc. and Lisa Walters-Hoffert dated as of March 9, 2020	10-Q	001-36395	05/14/2020	10.14(b)	
10.21*	Daré Bioscience, Inc. Change in Control Policy (as amended on April 29, 2024)	10-Q	333-251599	08/12/2024	10.6	
OTHER EXHIBITS						
19.1	Daré Bioscience, Inc. Amended and Restated Insider Trading Policy (October 22, 2024)					X
21.1	Subsidiaries of the registrant					X
23.1	Consent of Haskell & White LLP					X
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1#	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
97*	Dare Bioscience, Inc. Policy on Recovery of Erroneously Awarded Compensation	10-K				
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Calculation Linkbase Document					X

101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Label Linkbase Document	X
101.PRE	XBRL Taxonomy Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	X

§	All schedules (or similar attachments) have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The registrant will furnish copies of any schedules to the Securities and Exchange Commission upon request.
Δ	Confidential treatment has been requested or granted to certain confidential information contained in this exhibit.
+	Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.
*	Management contract or compensatory plan or arrangement
#	Furnished herewith. This certification is being furnished solely to accompany this report pursuant to U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated herein by reference into any filing of the registrant whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Daré Bioscience, Inc.

By: /s/ SABRINA MARTUCCI JOHNSON

President and Chief Executive Officer

Date: March 31, 2025

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ SABRINA MARTUCCI JOHNSON Sabrina Martucci Johnson	President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer) and Director	March 31, 2025
/s/ MARDEE HARING-LAYTON MarDee Haring-Layton	Chief Accounting Officer (Principal Accounting Officer)	March 31, 2025
/s/ WILLIAM H. RASTETTER William H. Rastetter, Ph.D.	Chairman of the Board and Director	March 31, 2025
/s/ JESSICA D. GROSSMAN Jessica D. Grossman, M.D.	Director	March 31, 2025
/s/ SUSAN L. KELLEY Susan L. Kelley, M.D.	Director	March 31, 2025
/s/ GREGORY W. MATZ Gregory W. Matz, CPA	Director	March 31, 2025
/s/ ROBIN STEELE Robin Steele, J.D., L.L.M.	Director	March 31, 2025

DARÉ BIOSCIENCE, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Daré Bioscience, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Daré Bioscience, Inc. and Subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024 and 2023, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring losses from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter – Estimating the Allocation of Transaction Price in Other Income Recognition

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Description of the Critical Audit Matter

During the year ended December 31, 2024, the Company entered into a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (US) LLC ("XOMA"). The Company received $22.0 million from XOMA in connection with entering into the royalty purchase agreements, which was determined as the transaction price. As described in Note 2 to the consolidated financial statements, the Company recognized other income in accordance with the principles outlined in ASC 610-20, Other Income – Gains and Losses from the Derecognition of Nonfinancial Assets, which requires the allocation of the transaction price to each performance obligation based on their relative standalone selling prices. The observable standalone selling prices were not available, and therefore the Company estimated these prices using the adjusted market assessment approach. This fair value approach requires management to make significant estimates and judgments, including the timing and amounts of projected net sales, probabilities of success in product development and regulatory approvals, and appropriate discount and royalty rates. Estimating probabilities of success for early-stage assets is inherently uncertain.

We identified the estimation of the allocation of the transaction price to multiple performance obligations in the Company's contract with XOMA as a critical audit matter due to the complexity involved in determining the standalone selling price of each performance obligation, which directly affects the amount of other income recognized in each period. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures to evaluate the reasonableness of management's significant estimates and assumptions, several of which extend many years into the future.

How the Critical Audit Matter Was Addressed in the Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. We obtained an understanding of the marketing status of the underlying commercialized product and an understanding of the development status and development plan for the two underlying product candidates, which included estimated timelines and milestones. We evaluated management's development of the market assessment approach, which includes the identification of key inputs and assumptions to the fair value model. We evaluated the sufficiency and appropriateness of the audit evidence supporting key inputs and assumptions to the fair value model. We also evaluated the appropriateness of the discount rate used by management in the fair value model and evaluated the expected future royalty rates. We performed independent mathematical accuracy tests of the Company's fair value model. We also performed substantive testing by recalculating the allocated transaction price using alternative assumptions, comparing the results to the Company's estimates, and assessing whether the other income recognized was consistent with the performance obligations completed during the period.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

We have served as the Company's auditor since 2023.

Irvine, California

March 31, 2025

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31,	
	2024	2023
Assets		
Current Assets		
Cash and cash equivalents	$ 15,698,174	$ 10,476,056
Other receivables	229,982	949,211
Prepaid expenses	2,519,707	6,118,272
Total current assets	18,447,863	17,543,539
Property and equipment, net	1,335,732	655,975
Deposits	12,027	1,163,477
Operating lease right-of-use assets	1,206,942	1,319,630
Other non-current assets	1,098,567	599,594
Total assets	$ 22,101,131	$ 21,282,215
Liabilities and stockholders' deficit		
Current Liabilities		
Accounts payable	$ 1,455,832	$ 3,385,551
Accrued expenses	3,042,918	2,889,005
Deferred grant funding	16,561,625	13,737,154
Current portion of lease liabilities	548,638	468,726
Total current liabilities	21,609,013	20,480,436
Deferred revenue, non-current	1,000,000	1,000,000
Liability related to the sale of future royalties, net	4,749,824	3,913,676
Lease liabilities, non-current	754,383	935,743
Total liabilities	28,113,220	26,329,855
Commitments and contingencies (Note 14)		
Stockholders' deficit		
Preferred stock, $0.01 par value, 5,000,000 shares authorized		
None issued and outstanding	—	—
Common stock, $0.0001 par value, 240,000,000 shares authorized, 8,700,386 and 8,331,161 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	870	833
Additional paid-in capital	169,705,480	166,548,454
Accumulated other comprehensive loss	(428,809)	(360,896)
Accumulated deficit	(175,289,630)	(171,236,031)
Total stockholders' deficit	(6,012,089)	(5,047,640)
Total liabilities and stockholders' deficit	$ 22,101,131	$ 21,282,215

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2024	2023
Revenue		
License fee revenue	$ —	$ 1,000,000
Milestone revenue	—	1,800,000
Royalty revenue	9,784	7,885
Total revenue	9,784	2,807,885
Operating expenses		
General and administrative	9,156,061	12,109,691
Research and development	14,205,208	21,538,074
License fee expense	100,000	100,000
Total operating expenses	23,461,269	33,747,765
Loss from operations	(23,451,485)	(30,939,880)
Other income (expense)		
Sale of royalty and milestone rights, net of transaction costs (Note 13)	20,379,376	—
Other (expense) income	(981,490)	778,489
Net loss	$ (4,053,599)	$ (30,161,391)
Net loss to common stockholders	$ (4,053,599)	$ (30,161,391)
Foreign currency translation adjustments	(67,913)	(9,585)
Comprehensive loss	$ (4,121,512)	$ (30,170,976)
Loss per common share - basic and diluted	$ (0.48)	$ (4.15)
Weighted average number of common shares outstanding:		
Basic and diluted	8,497,459	7,275,308

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity (Deficit)

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity (deficit)
Balance at December 31, 2022	**7,068,790**	**$ 707**	**$ 152,537,354**	**$ (351,311)**	**$ (141,074,640)**	**$ 11,112,110**
Stock-based compensation	—	—	2,530,684	—	—	2,530,684
Issuance of common stock from the exercise of warrants	112,793	11	1,299,365	—	—	1,299,376
Issuance of common stock, net of issuance costs	1,149,578	115	9,346,541	—	—	9,346,656
Issuance of common stock warrants, net of issuance costs	—	—	834,510	—	—	834,510
Net loss	—	—	—	—	(30,161,391)	(30,161,391)
Foreign currency translation adjustments	—	—	—	(9,585)	—	(9,585)
Balance at December 31, 2023	**8,331,161**	**$ 833**	**$ 166,548,454**	**$ (360,896)**	**$ (171,236,031)**	**$ (5,047,640)**
Stock-based compensation	—	—	2,203,257	—	—	2,203,257
Issuance cost on equity line paid in common stock	137,614	14	500,213	—	—	500,227
Issuance of common stock, net of issuance costs	109,655	11	453,568	—	—	453,579
Reverse stock split adjustment	121,956	12	(12)			—
Net loss	—	—	—	—	(4,053,599)	(4,053,599)
Foreign currency translation adjustments	—	—	—	(67,913)	—	(67,913)
Balance at December 31, 2024	**8,700,386**	**$ 870**	**$ 169,705,480**	**$ (428,809)**	**$ (175,289,630)**	**$ (6,012,089)**

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (4,053,599)	$ (30,161,391)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation expense	42,325	38,363
Right of use asset - operating lease	471,003	(861,706)
Stock-based compensation expense	2,203,256	2,530,684
Loss on disposal of property and equipment	600,000	—
Non-cash royalty revenue related to sale of future royalties	202	—
Non-cash interest expense on liability related to sale of future royalties	317,318	24,289
Changes in operating assets and liabilities:		
Other receivables	719,229	753,948
Prepaid expenses	3,598,565	547,714
Deposits	402,414	(1,152,974)
Other non-current assets	(33,746)	(10,300)
Operating lease liability	(459,763)	915,732
Accounts payable	(1,929,717)	1,357,601
Accrued expenses	171,473	(8,272,201)
Interest payable	520,816	—
Deferred grant funding	2,824,471	(4,566,413)
Net cash provided by (used in) operating activities	5,394,247	(38,856,654)
Cash flows from investing activities		
Purchases of property and equipment	(573,046)	(629,430)
Net cash used in investing activities	(573,046)	(629,430)
Cash flows from financing activities		
Net proceeds from issuance of common stock	453,579	9,346,656
Proceeds from the exercise of common stock warrants	—	1,299,376
Proceeds from the sale of future royalties, net	—	4,723,899
Repayment of liability on sale of future royalties	(2,189)	—
Issuance of note payable	561,663	601,174
Payments on note payable	(579,223)	(333,985)
Net cash provided by financing activities	433,830	15,637,120
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(67,913)	(9,585)
Net change in cash, cash equivalents and restricted cash	5,187,119	(23,858,549)
Cash, cash equivalents and restricted cash, beginning of year	10,811,056	34,669,605
Cash, cash equivalents and restricted cash, end of year	$ 15,998,174	$ 10,811,056
Reconciliation of cash, cash equivalents and restricted cash to amounts reported in the consolidated balance sheets:		
Cash and cash equivalents	$ 15,698,174	$ 10,476,056
Restricted cash included in other non-current assets	300,000	335,000
Total cash, cash equivalents and restricted cash	$ 15,998,174	$ 10,811,056
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ 358,315	$ 1,291,425
Issuance cost on equity paid in common stock	$ 500,227	$ —
Additions to property and equipment and reduction of deposits	$ 749,036	$ —
Issuance cost recorded under additional-paid-in-capital	$ —	$ 834,510

See accompanying notes.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Daré Bioscience, Inc. is a biopharmaceutical company driven by a mission to challenge the status quo, making women's health a priority. Daré Bioscience, Inc. and its wholly-owned subsidiaries operate one segment. In this report, the “Company” refers collectively to Daré Bioscience, Inc. and its wholly-owned subsidiaries, unless otherwise stated or the context otherwise requires.

The Company began assembling its diverse portfolio of assets in 2017 through acquisitions, exclusive in-licenses and other collaborations. The Company's programs target unmet needs in women's health, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause, and aim to enhance outcomes and convenience.

The Company’s primary operations have consisted of, and are expected to continue to consist primarily of, research and development activities to advance its product candidates through clinical development and regulatory approval.

The Company's portfolio of product candidates includes drug and drug/device product candidates and potential product candidates in various stages of development.

The first U.S. Food and Drug Administration (FDA)-approved product to emerge from the Company's portfolio is XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO. In March 2022, the Company entered into an exclusive global license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO. Under the license agreement, Organon (and/or its affiliates, agents or sublicensees) is solely responsible for the marketing, distribution and sale of XACIATO in the United States (and outside the U.S. if approved in non-U.S. jurisdictions in the future). In January 2024, Organon announced that XACIATO was available across the U.S. As described below, to provide funding for the development of the product candidates in the Company's pipeline, in April 2024, the Company entered into an agreement with XOMA (US) LLC (“XOMA”) whereby the Company sold its rights to all royalty and potential milestone payments based on net sales of XACIATO under its agreement with Organon, net of the Company's obligations to certain third parties, until XOMA receives a specified return on its investment, after which the Company will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or U.S. GAAP, as defined by the Financial Accounting Standards Board, or FASB.

Going Concern

The Company prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company has a history of losses from operations, net losses and negative cash flows from operations and expects significant losses from operations, net losses and negative cash flows from operations for at least the next several years as it develops and seeks to bring to market its existing product candidates and seeks to potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

At December 31, 2024, the Company had an accumulated deficit of approximately $175.3 million, unrestricted cash and cash equivalents of approximately $15.7 million, and a working capital deficit of approximately $3.2 million. The Company's unrestricted cash and cash equivalents at December 31, 2024 represented funds received under grant agreements that generally may be applied solely toward direct costs for carrying out the respective projects under those grant agreements. See Note 15, Grant Awards. For the year ended December 31, 2024, the Company incurred a net loss of $4.1 million and had positive cash flow from operations of approximately $5.4 million. The Company's net loss and cash flow from operations for the year ended December 31, 2024 were positively impacted

by the approximately $20.4 million of net proceeds the Company received from the sale in April 2024 of its rights to future royalty and milestone payments and revenue. See below and Note 13, Royalty Purchase Agreements.

Based on the Company's current operating plan estimates, the Company does not have sufficient cash to satisfy its working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. The Company will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current strategy.

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will not be able to continue development of its product candidates, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If the Company becomes unable to continue as a going concern, the Company may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its consolidated financial statements, and stockholders may lose all or part of their investment in the Company's common stock. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Segment Information

Operating segments are defined as components of an enterprise about which discrete financial information is available for evaluation the Chief Operating Decision Maker, or CODM, or decision-making group in making decisions on how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, or CEO. The CEO views the Company's operations and manages its business as one reportable and operating segment, Women's Health. See Note 16, "Segment Information," for additional information.

Reverse Stock Split

The Company effected a 1-for-12 reverse split of its issued common stock on July 1, 2024. At the effective time of the reverse stock split, every 12 shares of the Company’s common stock was automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split did not change the number of authorized shares or the par value per share of the Company’s common stock. See Note 9, Stockholders' Equity, for additional information regarding the reverse stock split.

All common stock share and per share data presented in the accompanying consolidated financial statements have been retroactively adjusted to reflect the impact of the reverse stock split for all periods presented, without giving effect to whole shares issued in lieu of fractional shares. In addition, proportionate adjustments were made in accordance with the applicable terms of outstanding stock options and warrants, the Company’s stock incentive plans and an existing agreement to the (a) per share exercise prices of, and the number of shares underlying, the Company’s outstanding stock options, (b) number of shares available for the grant of awards under the Company’s stock incentive plans, and (c) per share exercise prices of, and the number of shares underlying, outstanding warrants to purchase shares of the Company’s common stock and warrants potentially issuable by the Company in its sole discretion pursuant to an existing agreement.

Cash, Cash Equivalents and Restricted Cash

The Company considers cash and all highly liquid investments with an original maturity of three months or less to be cash and cash equivalents. The Company has an aggregate of approximately $0.3 million in restricted cash as of December 31, 2024 and 2023 related to (i) letters of credit established under real property leases for the Company's wholly-owned subsidiary, Dare MB Inc., that serve as security for potential future default of lease payments, and (ii) collateralized cash for the Company's credit cards. The restricted cash is unavailable for withdrawal or for general obligations and is included in other non-current assets on the Company's consolidated balance sheets.

Principles of Consolidation

The consolidated financial statements of the Company are stated in U.S. dollars. These consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. One wholly-owned subsidiary, Daré Bioscience Australia Pty LTD, operates primarily in Australia. The financial statements of the Company’s wholly-owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity’s functional currency and the reporting currency is

reported in Accumulated Other Comprehensive Loss. All intercompany transactions and accounts have been eliminated in consolidation.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally five years. Repair and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and right-of-use assets. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate, including its eventual residual value. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds its fair value. The Company did not recognize any impairment losses for either of the years ended December 31, 2024 or 2023. The Company recorded a loss on the disposal of a fixed asset of $0.6 million for the year ended December 31, 2024. No such losses were recorded during the year ended December 31, 2023.

Grant Funding

The Company receives certain research and development funding through grants issued by a division of the National Institutes of Health and the Gates Foundation, or the Foundation. Under the Foundation grant, which the Company considers to be a research and development contract under FASB Accounting Standards Codification, or ASC, Topic 730 *Research and Development*, the Company granted the Foundation a Humanitarian License which gives the Foundation the right to make the funded developments accessible at an affordable price to people within developing countries. Grants received by the Company that do not require the transfer of goods or services to a customer are accounted for by analogy to International Accounting Standards 20, *Accounting for Grants and Disclosure of Government Assistance*, or IAS 20. Under IAS 20, the Company recognizes grant funding in the statements of operations as a reduction to research and development expense as the related costs are incurred to meet those obligations over the grant period. The Company adopted this policy in 2018. For the years ended December 31, 2024 and December 31, 2023, the Company recognized approximately $8.8 million and $9.3 million, respectively, in the statements of operations as a reduction to research and development expense. Grant funding payments received in advance of research and development expenses incurred are recorded as deferred grant funding liability in the Company's consolidated balance sheets.

Use of Estimates

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, management's judgments with respect to its revenue arrangement, liability related to the sale of future royalties, valuation of stock-based awards and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates and could materially affect the reported amounts of assets, liabilities and future operating results.

Sale of Future Payments

On April 29, 2024, the Company entered into and closed a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA pursuant to which the Company sold its right, title and interest in the following to XOMA (i) all future net royalty and potential net milestone payments the Company would otherwise receive from Organon based on net sales of XACIATO, (ii) a portion of future net sales of Ovaprene and a portion of a potential future milestone payment the Company may receive under its license agreement with Bayer related to

Ovaprene, and (iii) a portion of future net sales of Sildenafil Cream. The Company received $22.0 million from XOMA in connection with entering into the royalty purchase agreements. Under the terms of the royalty purchase agreements, if XOMA receives total payments under the royalty purchase agreements equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to the Company for each successive $22.0 million XOMA receives under the royalty purchase agreements. If the Company earns any such payments, they will be accounted for as variable consideration under ASC 606, *Revenue Recognition,* and will be recorded as income when such payments are received. See Note 13, Royalty Purchase Agreements, for additional information regarding the terms of the royalty purchase agreements.

The Company evaluated the expected cash flows to XOMA from royalties and milestone payments expected to be earned on XACIATO, Ovaprene and Sildenafil Cream over the period that the Company expects it will take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements, and determined to allocate the $22.0 million it received from XOMA in connection with entering into the royalty purchase agreements, net of transaction costs of approximately $1.6 million, to the traditional royalty purchase agreement for XACIATO, and none of it to the synthetic royalty purchase agreement for Ovaprene and Sildenafil Cream. The cash flows to XOMA from royalties and milestone payments expected to be earned on Ovaprene and Sildenafil Cream are expected to be de minimis over the period that the Company expects it will take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements because, unlike XACIATO, Ovaprene and Sildenafil Cream are still in development stage and not commercial assets.

The Company determined that the traditional royalty purchase agreement represents a complete sale of a nonfinancial asset (the Company's right, title and interest in and to future payments related to commercial sales of XACIATO) for which XOMA bears all benefit and for which the Company has no obligations or involvement going forward, and therefore should be accounted for within the scope of ASC 610-20, Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets. The $22.0 million net of transaction costs of approximately $1.6 million, was recorded as other income on the Company's consolidated statements of operations and comprehensive loss.

Liability Related to the Sale of Future Royalties

In December 2023, the Company entered into a royalty interest financing agreement with United in Endeavor, or United, pursuant to which the Company sold to United an interest in royalty and milestone payments the Company receives based on net sales of XACIATO. The Company received $5.0 million from United in connection with entering into the royalty interest financing agreement. The Company evaluated the terms of the royalty interest financing agreement and concluded that its features were similar to those of a debt instrument. The Company recognized the $5.0 million it received as a liability on its consolidated balance sheet because the Company agreed to make payments to United until such time that United has received aggregate payments equaling a 12% internal rate of return on the $5.0 million. Interest expense for the liability related to the sale of future royalties is recognized using the effective interest rate method over the expected term of the royalty interest financing agreement.

The liability related to the sale of future royalties and related interest expense are based on current estimates of future royalties, which estimates are based on forecasts of XACIATO net sales. The Company periodically assesses the forecasted net sales and to the extent the amount or timing of estimated royalty payments are materially different than previous estimates, the Company will account for any such change by adjusting the liability related to the sale of future royalties and prospectively recognizing the related non-cash interest expense.

In connection with the royalty investment financing agreement the Company entered into, the Company issued a warrant to purchase up to an aggregate of 5.0 million shares of the Company's common stock. The warrant was allocated a relative fair value of approximately $0.8 million using a Black-Scholes option pricing model. The $0.8 million relative fair value of the warrant was recorded as a debt discount with an offset to additional paid in capital on the Company's 2023 consolidated balance sheets as the warrants were deemed to be equity classified.

Risks and Uncertainties

The Company will require approvals from the FDA, or foreign regulatory agencies prior to being able to sell any products. The Company received approval from the FDA for XACIATO in December 2021. There can be no assurance that the Company’s current or future product candidates will receive the necessary approvals. If the Company is denied regulatory approval of its product candidates, or if approval is delayed, it may have a material adverse impact on the Company’s business, results of operations and financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the ability to license product candidates, successfully develop product candidates, successfully commercialize approved products or enter into strategic relationships with third parties who are able to successfully

commercialize approved products, raise additional capital, compete with other products, and protect proprietary technology. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

Concentration of Credit Risk

The Company maintains cash balances at various financial institutions and such balances commonly exceed the $250,000 amount insured by the Federal Deposit Insurance Corporation. The Company also maintains money market funds at various financial institutions which are not federally insured although are invested primarily in the U.S. The Company has not experienced any losses in such accounts and management believes that the Company does not have significant risk with respect to such cash and cash equivalents.

Fair Value of Financial Instruments

GAAP defines fair value as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date, and also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available. The three-level hierarchy of valuation techniques established to measure fair value is defined as follows:

- Level 1: inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of assets or liabilities.
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables present the classification within the fair value hierarchy of financial assets and liabilities that are remeasured on a recurring basis as of December 31, 2024 and December 31, 2023. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) or using unobservable inputs (Level 3) as of December 31, 2024 or December 31, 2023.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at December 31, 2024				
Current assets:				
Cash equivalents [1]	$ 15,283,784	$ —	$ —	$ 15,283,784
Balance at December 31, 2023				
Current assets:				
Cash equivalents [1]	$ 9,982,079	$ —	$ —	$ 9,982,079

[1] Represents cash held in money market funds.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standard Update, or ASU, 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company adopted ASU 2023-07 on December 31, 2024, which adoption only impacted the Company's segment reporting disclosures. See Note 16, Segment Information, for disclosures related to the adoption of ASU 2023-07.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-3, Disaggregation of Income Statement Expenses. ASU 2024-3 requires new financial statement disclosures in tabular format, disaggregating information about prescribed categories underlying any relevant income statement expense captions. Additionally, in January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. The standard provides guidance to expand disclosures related to the disaggregation of income statement expenses. The standard requires, in the notes to the financial statements, disclosure of specified information about certain costs and expenses, which includes purchases of inventory, employee compensation, depreciation and intangible asset amortization included in each relevant expense caption. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027, on a retrospective or prospective basis, with early adoption permitted. The Company is assessing the guidance, noting the adoption impacts disclosure only.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. ASU 2023-09 will be effective for annual periods beginning January 1, 2025 and will be applied on a prospective basis with the option to apply the standard retrospectively. The Company is evaluating the disclosure impact of ASU 2023-09 on its consolidated financial statements.

The Company does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the consolidated financial statements.

Revenue Recognition

Under Accounting Standards Codification Topic 606, or ASC 606, the Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligations. At contract inception, the Company assesses the goods or services agreed upon within each contract, assesses whether each good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company develops estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Collaboration Revenues. The Company enters into collaboration and licensing agreements under which it out-licenses certain rights to its products or product candidates to third parties. The terms of these arrangements typically include payment of one or more of the following to the Company: non-refundable, up-front license fees; development, regulatory and/or commercial milestone payments; and royalties on net sales of licensed products. To date, the Company has not recognized any collaboration revenues.

License Fee Revenue. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. To date, the Company has recognized $11.0 million in license fee revenue, $10.0 million of which represents the upfront payment under its license agreement for XACIATO and $1.0 million of which represents the payment required by the first amendment to such license agreement entered into in July 2023.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has recognized approximately $18,000 in royalty revenue.

Product Supply. Arrangements that include a promise for future supply of product for commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company evaluates whether it is the principal or agent in the arrangement. The evaluation is based on the degree the Company controls the specified product at any time before transfer to the customer. Revenues are recognized on a gross basis if the Company is in the capacity of principal and on a net basis if the Company is in the capacity of an agent. To date, the Company has recognized approximately $205,000 in revenue along with $201,000 in other expense attributed to the cost of revenue associated with its product supply arrangement for XACIATO, which is recorded in other income in the Company's 2023 consolidated statement of operations and comprehensive loss. That arrangement was terminated effective December 14, 2023 and the Company will not recognize product supply revenue associated with that agreement in the future.

Bayer License. In 2020, the Company entered into a license agreement with Bayer Healthcare LLC, or Bayer, regarding the further development and commercialization of Ovaprene in the U.S. and received a $1.0 million upfront non-refundable license fee payment from Bayer (See Note 3, Strategic Agreements). The $1.0 million upfront payment is recorded as deferred license revenue in the Company's consolidated balance sheets at December 31, 2024 and 2023. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $20.0 million. The Company concluded that there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (i) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (ii) the termination of the agreement. To date, neither of the foregoing has occurred.

Under its license agreement with Bayer, the Company will also be entitled to receive (a) milestone payments totaling up to $310.0 million related to the commercial sales of Ovaprene, if all such milestones are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Milestone Payments. At the inception of each arrangement in which the Company is a licensor and that includes developmental, regulatory or commercial milestones, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Potential future milestone payments not within the Company's control, such as where achievement of the specified milestone depends on activities of a third party or regulatory approval, are not considered probable of being achieved until the specified milestone occurs. As of December 31, 2024, the Company has recognized $1.8 million of milestone payment revenues.

Potential future payments for variable consideration, such as commercial milestones, will be recognized when it is probable that, if recorded, a significant reversal will not take place. Potential future royalty payments will be recorded as revenue when the associated sales occur (See Note 3, Strategic Agreements).

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in other non-current assets as right-of-use, or ROU, lease assets, current portion of lease liabilities, and long-term lease liabilities on the Company's consolidated balance sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date based on the present value of lease payments over the lease term. If the lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease asset also includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease and the related payments are only included in the lease liability when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term (See Note 11, Leased Properties).

Australian Research and Development Tax Incentive Program

The Company is eligible under the Australian Research and Development Tax Incentive Program, or the Tax Incentive, to receive a cash refund from the Australian Taxation Office for eligible research and development expenditures. To be eligible, the Company must have revenue of less than AUD $20.0 million during the reimbursable period and cannot be controlled by income tax exempt entities. Grants received by the Company that do not require the transfer of goods or services to a customer are accounted for by analogy to IAS 20. Under IAS 20, the Company recognizes the Tax Incentive as a reduction to research and development expense when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured. The Company classifies its estimate for the Tax Incentive as other current assets on its consolidated balance sheets. For the years ended December 31, 2024 and 2023, the Company recognized approximately $46,000 and approximately $0.6 million, respectively, as a reduction to research and development expense for expenses incurred that it believes are eligible for the Tax Incentive. At December 31, 2024 and 2023, the Company recorded a receivable for the estimated Tax Incentive of approximately $46,000 and $0.6 million, respectively, in other receivables on the accompanying consolidated balance sheets.

Research and Development Costs

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses, manufacturing process-development and scale-up activities, fees paid to clinical and regulatory consultants, clinical trial and related clinical trial manufacturing expenses, fees paid to contract research organizations, or CROs, and investigative sites, transaction expenses incurred in connection with the expansion of the product portfolio through acquisitions and license and option agreements, milestone payments incurred or probable to be incurred for the Company's in-licensing arrangements, payments to universities under the Company’s license agreements and other outside expenses. Research and development costs are expensed as incurred. Nonrefundable advance payments, if any, for goods and services used in research and development are recognized as an expense as the related goods are delivered or services are performed.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the consolidated statements of operations.

Net Loss Per Share

Basic net loss attributable to common stockholders per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period without consideration of common stock equivalents. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods presented as the inclusion of all potential dilutive securities would have been antidilutive.

There were stock options exercisable into 883,334 and 788,569 shares of common stock outstanding at December 31, 2024 and 2023, respectively. There were warrants exercisable into 1,268,572 shares of common stock outstanding at each of the years ended December 31, 2024 and 2023. These securities were not included in the

computation of diluted loss per share because they are antidilutive, but they could potentially dilute earnings (loss) per share in future years.

Stock-Based Compensation

The Company records compensation expense for all stock-based awards granted based on the fair value of the award at the time of grant. Compensation expense is recognized in the consolidated statements of operations and comprehensive loss on a straight-line basis over the requisite service period of the award. The Company uses the Black-Scholes Pricing Model to determine the fair value of each of the awards which considers factors such as expected term, the volatility of the Company's common stock, risk free interest rate, and dividend yield. Due to the limited history of the Company, the simplified method was utilized in order to determine the expected term of the awards. The Company compared U.S. Treasury Bills in determining the risk-free interest rate appropriate given the expected term. The Company has not established and has no plans to establish, a dividend policy, and the Company has not declared, and has no plans to declare dividends in the foreseeable future and thus no dividend yield was determined necessary in the calculation of fair value.

Income Taxes

The Company accounts for income taxes using the asset and liability method in accordance with FASB ASC 740, Income Taxes. Under this method, deferred income taxes are provided to reflect the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company follows the two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not, that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount, which is more than 50% likely of being realized upon ultimate settlement. The Company considers many factors when evaluating and estimating the Company's tax positions and tax benefits, which may require periodic adjustments. At each of December 31, 2024 and 2023, the Company did not record any liabilities for uncertain tax positions.

During each of 2024 and 2023, the Company recorded no provision for income taxes. Management evaluated the Company’s tax positions and, as of December 31, 2024 and 2023, the Company had approximately $2.8 million and $2.6 million of unrecognized benefits, respectively. The tax years 2021 to 2023 and 2020 to 2023 remain open to examination by federal and state taxing authorities, respectively, while the statute of limitations for U.S. net operating losses generated remain open beginning in the year of utilization.

Indemnification Obligations

As permitted under Delaware law, the Company has entered into indemnification agreements with its officers and directors that provide that the Company will indemnify its directors and officers for certain expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by such director or officer in any action or proceeding arising out of their service as a director and/or officer. The term of the indemnification is for the officer’s or director’s lifetime. During the year ended December 31, 2024, the Company did not experience any losses related to those indemnification obligations. The Company does not expect significant claims related to these indemnification obligations, and consequently, has concluded the fair value of the obligations is not material. Accordingly, as of December 31, 2024 and 2023, no amounts have been accrued related to such indemnification provisions.

3. STRATEGIC AGREEMENTS

Strategic Agreements for Product Commercialization

Organon Exclusive License Agreement

In March 2022, the Company entered into an exclusive license agreement with Organon which became effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property controlled by the Company. In July 2022, the Company received a $10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue. In July 2023, the Company received a $1.0 million payment from Organon in connection with the amendment to the

license agreement the parties entered into, which was also recorded as license fee revenue. In the fourth quarter of 2023, in connection with the first commercial sale in the U.S. of XACIATO in accordance with the license agreement, as amended, the Company received the $1.8 million milestone payment from Organon.

Under the terms of the license agreement, as amended, the Company is entitled to receive tiered double-digit royalties based on net sales and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets.

At the inception of the license agreement, the Company concluded that the transaction price was $10.0 million and should not include the variable consideration related to unachieved development, regulatory, commercial milestones and future sales-based royalty payments. This consideration was determined to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue. The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. As a result of the $1.0 million payment in connection with the license agreement amendment and the $1.8 million milestone payment noted above, the transaction price was $12.8 million as of December 31, 2024.

The Company will recognize any consideration related to sales-based payments, including milestones and royalties which relate predominantly to the license granted, at the later of (i) when or as the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Refer to Note 13, Royalty Purchase Agreements, regarding the Company's sale to XOMA of all the Company's right, title and interest in and to, from and after April 1, 2024, all net royalty and potential net milestone payments from Organon based on net sales of XACIATO.

The Company was responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumed such responsibilities, which occurred in December 2023. Prior to that time, Organon purchased all of its product requirements of XACIATO from the Company at a transfer price equal to the Company's manufacturing costs plus a single-digit percentage markup.

Unless terminated earlier, the agreement will expire on a product-by-product and country-by-country basis upon expiration of the applicable royalty period for each licensed product. In addition to customary termination rights for both parties, Organon may terminate the agreement in its entirety or on a country-by-country basis at any time in Organon's sole discretion on 120 days' advance written notice.

Bayer HealthCare License Agreement

In January 2020, the Company entered into a license agreement with Bayer, regarding the further development and commercialization of Ovaprene in the U.S. The Company received a $1.0 million upfront non-refundable license fee payment from Bayer and Bayer agreed to support the Company in development and regulatory activities by providing the equivalent of two experts to advise the Company in clinical, regulatory, preclinical, commercial, CMC and product supply matters. The Company is responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $20.0 million, referred to as the $20.0 million fee. After payment of the $20.0 million fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S. Such license would be exclusive as to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with the Company with regard to development.

The Company concluded there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (i) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (ii) the termination of the agreement. As of December 31, 2024, neither of the foregoing had occurred. The $1.0 million payment is recorded as non-current deferred license revenue in the Company's consolidated balance sheets at December 31, 2024 and 2023.

If Bayer elects to make the license effective, the Company will be entitled to receive (a) a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S. and escalating milestone payments based on annual net sales of Ovaprene during a calendar year, totaling up to $310.0 million if all such milestones, including the first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based

on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Refer to Note 13, Royalty Purchase Agreements, regarding XOMA's rights to a portion of potential future payments from Bayer under the Company's license agreement with Bayer.

The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S. or 15 years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days' notice and the agreement will automatically terminate if the Company does not receive the $20.0 million fee if and when due.

Strategic Agreements for Pipeline Development

Theramex Co-Development and Licensing Agreement

In February 2025, the Company entered into a co-development and licensing agreement with Theramex for a potential first-in-category biodegradable contraceptive implant called Casea S recently acquired by Theramex. Under the agreement, the Company received a royalty-free, exclusive, fully paid up, sublicensable license to the U.S. patents Theramex recently acquired for Casea S. Given that the product is in an ongoing Phase 1 study that is funded by a grant, there are no development costs for the Company or Theramex at this time. If the Company determines that the results from the study are positive, it would be responsible for conducting a Phase II study in the U.S., and funding for such study and for a future Phase III study in the U.S. will be shared by the Company and Theramex on terms to be agreed upon by the parties, taking into account the size of the opportunity for Casea S in the respective markets.

Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement

In August 2023, the Company entered into a license agreement with Douglas Pharmaceuticals Limited, or Douglas, under which the Company acquired the exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia and other HPV-related pathologies, and an agreement with The University of Manchester, pursuant to which The University of Manchester consented to Douglas' sublicense to the Company of certain rights it previously granted to Douglas and agreed to grant the Company a direct license to such rights if its license agreement with Douglas is terminated. Under the Company's agreement with Douglas, it received an exclusive, royalty-bearing license to research, develop and commercialize the licensed intellectual property in the United States for the treatment or prevention of all indications for women in female reproductive health. As a result of this license, the Company commenced its DARE-HPV program. The Company is entitled to sublicense the rights granted to it under the agreement.

Under the terms of the Douglas agreement, the Company agreed to make potential future payments of up to $5.25 million in the aggregate upon achievement of certain development and regulatory milestones, and of up to $64.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement. The development and regulatory milestones may be paid in shares of the Company’s common stock, in the Company's sole discretion subject to specified limitations. Additionally, Douglas is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on annual net sales of products and processes covered by the licenses granted under the agreement. As of December 31, 2024, no payments had been made under the Douglas agreement.

Hennepin License Agreement

In August 2022, the Company entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which the Company acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. As a result of this license, the Company commenced its DARE-GML program. Under the agreement, the Company received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. The Company is entitled to sublicense the rights granted to it under the agreement.

Under the terms of the license agreement, the Company agreed to make potential future payments of up to $6.25 million in the aggregate upon achievement of certain development and regulatory milestones, and up to $45.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by

the licenses granted under the agreement, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock. Additionally, Hennepin is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement. As of December 31, 2024, no payments have been made under this agreement.

MBI Acquisition

In November 2019, the Company acquired Dare MB Inc., or MBI, to secure the rights to develop a long-acting reversible contraception method, that a woman can turn on or off herself, according to her own needs. This candidate is now known as DARE-LARC1.

Under the terms of the merger agreement, the Company agreed to pay former MBI stockholders: (a) up to $46.5 million contingent upon the achievement of specified funding, product development and regulatory milestones; (b) up to $55.0 million contingent upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property the Company acquired in the merger; and (c) tiered royalty payments ranging from low single-digit to low double-digit percentages based on annual net sales of such products sold by the Company (but not by sublicensee) and a percentage of sublicense revenue related to such products.

In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events. In accordance with the terms of the merger agreement, the Company's board of directors elected to pay a portion of these milestone payments in shares of the Company's common stock, and in September 2021, the Company issued approximately 58,334 shares of its common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders' representative in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021. As of December 31, 2024, no additional payments have been made under this agreement.

TriLogic and MilanaPharm License Agreement / Hammock Assignment Agreement

In December 2018, the Company entered into an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, the Company acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In XACIATO, this proprietary technology is formulated with clindamycin for the treatment of bacterial vaginosis. In December 2019, the Company entered into amendments to each of the Assignment Agreement and License Amendment. In September 2021, the Company entered into a second amendment to the License Agreement. In March 2022, the Company entered into a Consent, Waiver and Stand-By License Agreement with TriLogic, MilanaPharm and Organon, which further amended the License Agreement.

Under the terms of the License Agreement, the Company paid clinical and regulatory development milestones of $300,000 in the aggregate to MilanaPharm, the final payment of which was made in 2021, and $500,000 in connection with the first commercial sale in the United States of XACIATO in the fourth quarter of 2023. Additionally, the Company may pay up to $250,000 upon the first commercial sale in the United States of successive licensed products for each vaginal or urological use. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products the Company must pay MilanaPharm $1.0 million. MilanaPharm is also eligible to receive (a) a low double-digit percentage of all income received by the Company or its affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions, and (b) high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes.

Hammock assigned and transferred to the Company all of its right, title and interest in and to the MilanaPharm license agreement and agreed to cooperate to transfer to the Company all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan. Hammock is eligible to receive up to $1.1 million

in the aggregate upon achievement of certain clinical and regulatory development milestones, $850,000 of which had been paid as of December 31, 2024.

Pear Tree Acquisition

In May 2018, the Company acquired Pear Tree Pharmaceuticals, Inc., or Pear Tree, to secure exclusive, sublicensable, worldwide rights under certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration. This acquisition led to the Company's DARE-VVA1 program.

Under the terms of the merger agreement, the Company agreed to pay the former stockholders of Pear Tree: (a) up to $15.5 million in the aggregate upon achievement of certain clinical development and regulatory milestones by licensed products, and (b) up to $47.0 million in the aggregate upon achievement of certain commercial milestones by licensed products. Additionally, the former stockholders of Pear Tree are eligible to receive tiered royalties based on single-digit to low double-digit percentages of annual net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, and a portion of royalties the Company receives from sublicensees. Both the milestone and royalty payments may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the merger agreement. Under the merger agreement, in addition to customary royalty reductions and offsets, royalty payments and payments based on income received from sublicensees of licensed products made by the Company to Pear Tree's licensors are creditable against all royalty and sublicense revenue share payments payable to the former stockholders of Pear Tree.

The Company agreed to pay licensors of Pear Tree (a) up to approximately $3.2 million in the aggregate upon achievement of certain clinical development, regulatory and commercial milestones by each licensed product, and (b) semi-annual royalties based on a single-digit percentage of net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, or a portion of any royalties the Company or its affiliates receives from sublicensees, and a low double-digit percentage of all sublicensing fees or other lump sum payments or compensation the Company receives from sublicensees, subject to customary exclusions. The milestone payments to the licensors of Pear Tree may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the license agreements. Portions of certain milestone payments made to Pear Tree's licensors may be creditable against royalty payments due to Pear Tree's licensors. As of December 31, 2024, no payments have been made under this agreement.

Catalent JNP License Agreement

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc., or Catalent, under which Catalent granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, to make, have made, use, have used, sell, have sold, import and have imported products and processes, and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Catalent to make, have made, use, have used, sell, have sold, import and have imported products and processes. As a result of this license agreement, the Company commenced its DARE-HRT1, DARE-FRT1 and DARE-PTB1 programs. The Company is entitled to sublicense the rights granted to it under this agreement.

Under the terms of the license agreement, the Company paid a $250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement and will pay a $100,000 annual license maintenance fee on each anniversary of the date of the agreement. The annual maintenance fee will be creditable against royalties and other payments due to Catalent in the same calendar year but may not be carried forward to any other year. Catalent is eligible to receive up to (a) $13.5 million in the aggregate in payments based on the achievement of specified development and regulatory milestones, $1.0 million of which had been paid as of December 31, 2024; and (b) up to $30.3 million in the aggregate in payments based on the achievement of specified commercial sales milestones for each product or process covered by the licenses granted under the agreement. Additionally, Catalent is eligible to receive mid single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, the Company will pay Catalent a low double-digit percentage of all sublicense income the Company receives for the sublicense of rights under the agreement to a third party.

Adare Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharmaceuticals USA, Inc., or Adare, for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which the Company

refers to as DARE-204 and DARE-214, respectively). The agreement, as amended, provides the Company with an option to negotiate an exclusive, worldwide, royalty-bearing license, with rights to sublicense, for the programs if the Company funds the conduct of specified development work. The Company has no obligation to exercise its option.

SST License and Collaboration Agreement

In February 2018, the Company entered into a license and collaboration agreement with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC, referred to collectively as SST, under which the Company received an exclusive, royalty-bearing, sublicensable license to develop and commercialize, in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of female sexual arousal disorder and/or female sexual interest/arousal disorder, or the Field of Use, SST's topical formulation of Sildenafil Cream, 3.6% as it existed as of the effective date of the agreement, or any other topically applied pharmaceutical product containing sildenafil or a salt thereof as a pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen, or the Licensed Products.

SST will be eligible to receive payments of up to $18.0 million in the aggregate upon achievement of certain clinical and regulatory milestones in the U.S. and worldwide, and up to $100.0 million in the aggregate upon achievement of certain commercial sales milestones. If the Company enters into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST. Additionally, SST is eligible to receive tiered royalties based on percentages of annual net sales of licensed products in the single-digit to mid double-digits subject to customary royalty reductions and offsets, and a percentage of sublicense revenue. As of December 31, 2024, $1.0 million became payable under this agreement and was subsequently paid in February 2025.

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., or ADVA-Tec, under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide.

Under the terms of the license agreement, the Company will pay ADVA-Tec (a) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones, $1.2 million of which has been paid; and (b) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones.

Additionally, ADVA-Tec is eligible to receive royalties based on aggregate annual net sales of Ovaprene in specified regions at a royalty rate that will vary between 1% and 10% and will increase based on various net sales thresholds, subject to customary reductions and offsets.

If the Company sublicenses its rights under the agreement, in lieu of royalty payments to ADVA-Tec, ADVA-Tec is eligible to receive a double-digit percentage of sublicense revenue received by the Company during the royalty term; provided, however, that for sublicense revenue the Company receives prior to the first commercial sale of a licensed product that represents an upfront payment or license fee due on or around the effective date of the sublicense, ADVA-Tec is eligible to receive a single-digit percentage of that sublicense revenue. As of December 31, 2024, only the $1.2 million in aggregate milestone payments noted above have been made.

4. PREPAID EXPENSES

Prepaid expenses consisted of the following:

	As of December 31,	
	2024	2023
Prepaid clinical expense	$ 1,290,605	$ 5,023,140
Prepaid development expense	663,723	376,959
Prepaid insurance expense	398,950	472,922
Prepaid legal and professional expenses	166,429	245,251
Total prepaid expenses	$ 2,519,707	$ 6,118,272

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consist of the following:

	As of December 31,	
	2024	2023
Assets under construction	$ 1,229,165	$ 600,000
IT equipment	37,239	51,978
Leasehold improvements	40,284	42,188
Lab equipment	204,938	107,511
	$ 1,511,626	$ 801,677
Less– accumulated depreciation	(175,894)	(145,702)
Property and equipment, net	$ 1,335,732	$ 655,975

Depreciation expense was $42,325 and $38,363 for the years ended December 31, 2024 and 2023, respectively.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2024	2023
Accrued clinical expense	$ —	$ 1,195,744
Accrued compensation and benefits	805,612	805,412
Accrued development expense	1,258,435	547,490
Accrued royalties payable	—	6,504
Insurance financing payable	249,628	267,188
Other accruals	662,576	—
Accrued license fee expense	66,667	66,667
Total accrued expenses	$ 3,042,918	$ 2,889,005

7. VENDOR CONCENTRATION

The Company had two major vendors that accounted for approximately 15% and 12% of the Company's research and development expenditures for the year ended December 31, 2024, and 21% and 3% of the Company's research and development expenditures for the year ended December 31, 2023. The same vendors accounted for 0% of the Company's total accounts payable and accrued expenses as of each of December 31, 2024 and 2023. The Company continues to maintain its relationship with these vendors and anticipates incurring significant expenses with these vendors over the next 12 months.

8. INCOME TAXES

The components of loss from continuing operations before provision for income taxes consists of the following (in thousands):

	Years Ended December 31,	
	2024	2023
Domestic	$ 3,822	$ 29,099
Foreign	230	1,060
Loss before taxes	$ 4,052	$ 30,159

The difference between the provision (benefit) for income taxes and the amount computed by applying the U.S. federal income tax rate for the years ended December 31, 2024 and 2023 are as follows:

	Years Ended December 31,	
	2024	2023
Federal statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	(6.26)%	0.84 %
State tax rate change	29.65 %	1.15 %
Permanent differences	(2.21)%	(0.02)%
Research and development credit	31.74 %	7.47 %
Stock compensation	(5.49)%	(0.75)%
Other	(9.49)%	(3.04)%
Change in valuation allowance	(58.98)%	(26.65)%
Effective income tax rate	(0.04)%	— %

The major components of the Company's deferred tax assets as of December 31, 2024 and 2023 are shown below (in thousands).

	2024	2023
Net operating loss carryforwards	$ 86,589	$ 86,182
Research and development credit carryforwards	11,836	10,868
Capitalized research and development costs	12,614	12,570
Other	59	41
Stock compensation	3,570	2,618
Total deferred tax assets	114,668	112,279
Valuation allowance	(114,668)	(112,279)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Under applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a valuation allowance of $114.7 million and $112.3 million was established at December 31, 2024 and 2023, respectively, to offset the net deferred tax assets. When and if management determines that it is more likely than not that the Company will be able to utilize the deferred tax assets prior to their expiration, the valuation allowance may be reduced or eliminated.

The increase in valuation allowance of approximately $2.4 million and $8.0 million for the years ended December 31, 2024 and 2023, respectively, is primarily related to an increase in net operating losses and R&D credits generated during the year and changes in state tax rates.

The Company has U.S. federal net operating loss, or NOL, carryforwards available at December 31, 2024 of approximately $315.2 million of which $1.1 million begin expiring in 2025 unless previously utilized and $139.8 million that do not expire. The Company has state NOL carryforwards of $298.4 million that begin expiring in 2031 unless previously utilized. The Company has U.S. federal research credit carryforwards available at December 31, 2024 of approximately $11.6 million that begin expiring in 2027 unless previously utilized. The Company has state research credit carryforwards of $2.5 million of which $0.2 million begin expiring in 2027 unless previously utilized. These federal and state research and development credits are subject to a 20% reserve under FASB ASC 740. The difference between federal and state NOL carryforwards is primarily due to previously expired state NOL carryforwards.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not yet completed an evaluation of ownership changes. To the extent an ownership change occurs, the NOL and credit carryforwards and other deferred tax assets may be subject to limitations.

A reconciliation of the beginning and ending amount of uncertain tax benefits is as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Beginning uncertain tax benefits	$ 2,617	$ 2,316
Current year - increases	237	347
Prior year - reductions	(30)	(46)
Ending uncertain tax benefits	$ 2,824	$ 2,617

Included in the balance of uncertain tax benefits at December 31, 2024 are $2.8 million of tax benefits that, if recognized, would result in a reduction of the gross deferred tax asset, offset fully by valuation allowance and have no net impact on the financial statements. The Company anticipates that no material amounts of unrecognized tax benefits will be settled within 12 months of the reporting date.

The Company's policy is to record estimated interest and penalties related to uncertain tax benefits as income tax expense. As of December 31, 2024 and 2023, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The tax years 2020 through 2023 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the U.S. The statute of limitations for U.S. net operating losses utilized in future years will remain open beginning in the year of utilization.

No additional provision has been made for U.S. income taxes related to undistributed foreign earnings of the Company’s wholly-owned Australian subsidiary or for unrecognized deferred tax liabilities for temporary differences related to investments in subsidiaries. As such, earnings are expected to be permanently reinvested, the investments are permanent in duration, or the Company has estimated that no additional tax liability will arise as a result of the distribution of such earnings. A liability could arise if amounts are distributed by the subsidiary or if the subsidiary is ultimately disposed. It is not practical to estimate the additional income taxes, if any, related to permanently reinvested earnings. There are no unremitted earnings as of December 31, 2024.

9. STOCKHOLDERS’ EQUITY

Reverse Stock Split

On July 1, 2024, the Company effected a 1-for-12 reverse split of its issued common stock. At the effective time of the reverse stock split, every 12 shares of the Company’s common stock was automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split reduced the number of issued and outstanding shares of the Company’s common stock from approximately 101.1 million to approximately 8.5 million. The reverse stock split did not change the number of authorized shares or the par value per share of the Company’s common stock.

Equity Line

On October 21, 2024, the Company entered into a purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the purchase agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million of the Company’s common stock. Such sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company’s sole discretion, over the 24-month period commencing on November 27, 2024. In connection with entering into the purchase agreement, the Company issued 137,614 shares of its common stock to Lincoln Park in consideration for its commitment to purchase shares thereunder.

September 2023 Registered Direct Offering

In August 2023, the Company entered into a securities purchase agreement with an institutional investor and an investor affiliated with Douglas for the purchase and sale of 833,334 shares of the Company's common stock and warrants to purchase additional shares of the Company's common stock in a registered direct offering priced at-the-market under Nasdaq rules. The offering closed on September 1, 2023. Each warrant is exercisable for one share of

the Company's common stock. The terms of the warrants are further described below in this Note 9. The offering price was $8.40 per share of common stock and accompanying warrant. The aggregate gross proceeds to the Company from the offering were $7.0 million, and net proceeds were approximately $7.0 million. The offering was made pursuant to the Company's registration statement on Form S-3 (File No. 333-254862), filed with the SEC on March 30, 2021, and declared effective by the SEC on April 7, 2021, and a prospectus supplement thereunder.

March 2023 ATM Sales Agreement

In March 2023, the Company entered into a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, and Cantor Fitzgerald & Co., or Cantor, to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program under which Stifel and Cantor act as the Company's agent. The Company agreed to pay a commission equal to 3% of the gross proceeds of any common stock sold under the agreement or such lower amount as the Company and Stifel and Cantor agree, plus certain legal expenses. In April 2024, the Company and Cantor mutually agreed to terminate the sales agreement with respect to Cantor. Through and including May 10, 2024, shares of the Company's common stock sold under the sales agreement were offered and sold under the Company's shelf registration statement on Form S-3 (File No. 333-254862), the base prospectus included therein, originally filed with the SEC on March 30, 2021 and declared effective by the SEC on April 7, 2021, and the prospectus supplements thereto, the most recent of which was dated March 28, 2024 relating to the offering of up to $19.0 million of shares of the Company's common stock. From and after May 11, 2024, shares of the Company's common stock sold under the sales agreement were and will be offered and sold under the Company's shelf registration statement on Form S-3 (File No. 333-278380), the base prospectus included therein, originally filed with the SEC on March 29, 2024 and declared effective by the SEC on May 10, 2024, the prospectus supplement thereto dated May 10, 2024 relating to the offering of up to $18.1 million of shares of the Company's common stock, and any subsequent prospectus supplement related to the offering of shares of the Company's common stock under the sales agreement. During the years ended December 31, 2024 and 2023, the Company sold 109,655 and 316,244 shares of common stock, respectively, under the sales agreement for net proceeds of approximately $0.5 million and $2.3 million, respectively.

Common Stock Warrants

December 2023 Warrants

In connection with the royalty interest financing agreement the Company entered into in December 2023, the Company issued a warrant to purchase up to an aggregate of 422,805 shares of the Company's common stock. The warrant has a term of five years from the date of issuance and an exercise price of $4.10 per share, subject to customary adjustment for stock splits and similar transactions. A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company's outstanding common stock immediately after exercise. The warrant includes certain rights in favor of the holder upon a “fundamental transaction” as described in the warrant, including the right of the holder to receive from the Company or the successor entity an amount of cash equal to the Black-Scholes value (as described in the warrants) of the unexercised portion of the warrant on the date of the consummation of such fundamental transaction.

The warrant was allocated a value of $0.8 million using a Black-Scholes option pricing model based on the relative fair value method. The Black-Scholes model used the following assumptions: expected volatility: 85.91%; risk-free interest rate: 4.05%; expected dividend yield: 0%; and expected term: 5 years. The warrant was deemed to be classified as equity and recorded within additional paid in capital on the consolidated balance sheets. As of December 31, 2024, no portion of the warrant had been exercised.

September 2023 Warrants

In connection with the registered direct offering completed in September 2023, the Company issued warrants to purchase up to an aggregate of 845,225 shares of the Company's common stock. The warrants became exercisable on March 1, 2024, expire March 1, 2029 and have an exercise price of $9.11 per share, subject to customary adjustment for stock splits and similar transactions. A holder (together with its affiliates) may not exercise any portion of a warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company's outstanding common stock immediately after exercise. The warrants include certain rights in favor of the holders upon a “fundamental transaction” as described in the warrants, including the right of the holders to receive from the Company or the successor entity an amount of cash equal to the Black-Scholes value (as described in the warrants) of the unexercised portion of the warrants on the date of the consummation of such fundamental transaction.

The warrants were allocated a value of $2.9 million using a Black-Scholes option pricing model based on the relative fair value method as they were issued with common stock. The Black-Scholes model used the following assumptions: expected volatility: 87.77%; risk-free interest rate: 4.29%; expected dividend yield: 0%; and expected term: 5.5 years. The warrants were deemed to be classified as equity and recorded within additional paid in capital on the consolidated balance sheets. As of December 31, 2024, none of the warrants have been exercised.

February 2018 Warrants

In connection with an underwritten public offering in February 2018, the Company issued to the investors in that offering, warrants exercisable through February 2023 with an initial exercise price of $36.00 per share. The Company estimated the fair value of the warrants as of February 15, 2018 to be approximately $3.0 million which was recorded in equity as of the issuance date. The warrants included a price-based anti-dilution provision, which resulted in automatic reductions to the exercise price of the warrants in April 2019 and July 2020 to $11.76 per share and $11.52 per share, respectively. In January 2023, warrants to purchase 112,793 shares of common stock were exercised for gross proceeds of approximately $1.3 million and the remaining unexercised warrants expired in February 2023.

Summary of Warrant Activity

A summary of warrant activity during the years ended December 31, 2024 and 2023 is presented below:

	Common Stock			
	Number of Shares Underlying Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value
Outstanding, December 31, 2022	115,085	$ 12.03	0.23	$ —
Granted	1,268,030			
Exercised	(112,793)			
Forfeited or expired	(1,750)			
Outstanding, December 31, 2023	1,268,572	$ 7.49	5.11	$ —
Granted	—	—		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding and exercisable, December 31, 2024	1,268,572	$ 7.49	4.10	$ —

Common Stock

The authorized capital of the Company consists of 240,000,000 shares of common stock with a par value of $0.0001 per share and 5,000,000 shares of preferred stock with a par value of $0.01 per share. The issued and outstanding common stock of the Company consisted of 8,700,386 and 8,331,161 shares of common stock as of December 31, 2024 and 2023, respectively. There were no shares of preferred stock issued or outstanding as of December 31, 2024 or 2023.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2024:

Common stock reserved for issuance upon exercise of warrants outstanding	1,268,572
Common stock reserved for issuance upon exercise of options outstanding	883,334
Common stock reserved for future equity awards	465,751
Total	2,617,657

10. STOCK-BASED COMPENSATION

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan, or the ESPP, became effective in April 2014, but no offering period has been initiated thereunder since January 2017. In June 2024, the Company's board of directors suspended the ESPP. There was no stock-based compensation related to the ESPP for the years ended December 31, 2024 or December 31, 2023.

Amended and Restated 2014 Stock Incentive Plan

The Amended and Restated 2014 Stock Incentive Plan, or the Amended 2014 Plan, provided for the grant of stock-based awards to employees, directors, consultants and advisors. As a result of the approval of the 2022 Plan (as defined below) by the Company's stockholders on June 23, 2022, no further awards have been or will be granted under the Amended 2014 Plan since June 23, 2022. Outstanding awards previously granted under the Amended 2014 Plan continue to remain outstanding in accordance with their terms.

2022 Stock Incentive Plan

In April 2022, the Company's board of directors approved the Daré Bioscience, Inc. 2022 Stock Incentive Plan, or the 2022 Plan, which was subsequently approved by the Company's stockholders on June 23, 2022, and became effective as of that date. The 2022 Plan provides for the grant of stock-based incentive awards to employees, directors, consultants, and advisors.

The number of shares of common stock authorized for issuance under the 2022 Plan is (a) 843,108; plus (b) up to 512,056 shares subject to awards granted under the Amended 2014 Plan or the 2007 Stock Incentive Plan that expire, terminate or are otherwise forfeited on or after June 23, 2022. Options granted are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. Stock options generally vest over a four-year term. The exercise price of each option is determined by the Company's board of directors or its compensation committee based on the estimated fair value of the Company's stock on the date of grant.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Company's stock incentive plans and related information for the years ended December 31, 2024 and 2023. The exercise price of all options granted during the years ended December 31, 2024 and 2023 was equal to the market value of the Company's common stock on the date of grant. As of December 31, 2024, unamortized stock-based compensation expense of approximately $2.2 million will be amortized over the weighted average period of 1.1 years. The number of shares of common stock available for future awards granted under the 2022 Plan as of December 31, 2024 was 465,751.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value *
Outstanding at December 31, 2022	551,003	$ 19.18		
Granted	238,120	13.62		
Exercised	—	—		
Cancelled/forfeited	(525)	14.07		
Expired	(29)	13.92		
Outstanding at December 31, 2023	788,569	17.50		
Granted	228,060	5.45		
Exercised	—	—		
Canceled/forfeited	(79,148)	12.90		
Expired	(54,147)	21.16		
Outstanding at December 31, 2024	883,334	$ 14.58	6.73	$ —
Options exercisable at December 31, 2024	593,118	$ 16.96	5.81	$ —
Options vested and expected to vest at December 31, 2024	593,118	$ 16.96	5.81	$ —

**The aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's common stock exceeded the exercise price of the stock options at December 31, 2024 for those stock options for which the quoted market price was in excess of the exercise price.*

The weighted average grant-date fair value of stock options granted during at December 31, 2024 and 2023 was $4.10 and $11.28, respectively.

Compensation Expense

Total stock-based compensation expense related to stock options granted to employees and directors recognized in the consolidated statements of operations and comprehensive loss is as follows:

	Years Ended December 31,	
	2024	2023
Research and development	$ 833,689	$ 823,148
General and administrative	1,369,567	1,707,536
Total	$ 2,203,256	$ 2,530,684

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of their service on the Company's board of directors during the years ended December 31, 2024 and 2023 is as follows:

	2024	2023
Expected life in years	6.0	6.0
Risk-free interest rate	4.13 %	3.56 %
Expected volatility	90 %	107 %
Dividend yield	0.0 %	0.0 %

11. LEASED PROPERTIES

Clean Room Space

On July 24, 2024, the Company entered into a scope of work (the "SOW") with an unrelated third party for a controlled clean room space in Burlington, Massachusetts. The SOW became effective upon the execution of an associated License and Services Agreement, which governs the SOW. The term of the SOW is 22 months and commenced on March 1, 2025. Upon execution of the SOW, the Company made a payment of approximately $459,000. Fixed payments will be due at the beginning of each calendar quarter and variable amounts related to support services will be due monthly based on services provided during the preceding month. The Company's total

obligation in respect of the fixed payments due under the SOW is approximately $3.5 million. The SOW may be renewed each year and if renewed, the fixed payment amount may increase yearly by up to 5%.

General Office Space

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018. In February 2022, the Company entered into an amendment to extend the term of the lease through August 31, 2024. On March 8, 2024, the Company entered into another amendment to extend the term of the lease for three years such that the term now expires on October 31, 2027, which resulted in additional operating lease liabilities and ROU assets of approximately $0.4 million in March 2024.

MBI, a wholly-owned subsidiary the Company acquired in November 2019, leases general office and laboratory space in Lexington, Massachusetts. The lease commenced on November 1, 2023 for a term of three years, expiring on December 31, 2026, and resulted in an increase in operating lease liabilities and ROU assets of approximately $0.4 million.

Under the terms of each lease, the lessee pays base annual rent (subject to an annual fixed percentage increase), plus property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The leases do not require material variable lease payments, residual value guarantees or restrictive covenants.

The leases do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company uses an incremental borrowing rate consisting of the current prime rate plus 200 basis points for operating leases. The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At December 31, 2024, the Company reported operating lease ROU assets of approximately $1.2 million in other non-current assets, approximately $0.5 million in current portion of lease liabilities, and approximately $0.8 million in lease liabilities long-term in the consolidated balance sheets.

Total operating lease costs were approximately $0.8 million and $0.6 million for the years ended December 31, 2024 and 2023, respectively. Operating lease costs consist of monthly lease payments expense, common area maintenance and other repair and maintenance costs and are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $0.6 million and $0.4 million for the years ended December 31, 2024 and 2023, respectively, and these amounts are included in operating activities in the consolidated statements of cash flows. At December 31, 2024, operating leases had a weighted average remaining lease term of 2.42 years and a weighted average interest rate of 10.50%.

At December 31, 2024, future minimum lease payments under the Company's operating leases are as follows:

Year ending December 31,	
2025	$ 660,000
2026	680,000
2027	130,000
Total future minimum lease payments	1,470,000
Less: accreted interest	167,000
Total operating lease liabilities	$ 1,303,000

12. ROYALTY INTEREST FINANCING

On December 21, 2023, the Company entered into a royalty interest financing agreement, or the Royalty Interest Agreement, with United in Endeavour, LLC, or UiE, under which UiE acquired a portion of the Company's royalty interest in XACIATO. The Company received $5.0 million from UiE when the parties entered into the Royalty Interest Agreement (the "Initial Investment"), and between January 1, 2024 and December 31, 2026, the Company may, in its sole discretion, but subject to XOMA's prior written consent (see Note 13, Royalty Purchase Agreements),

elect to receive three additional payments (each a "Supplemental Investment") from UiE of up to an aggregate of $7.0 million, for a total of up to $12.0 million.

Under the Royalty Interest Agreement, the Company agreed to make the following payments to UiE, until such time when UiE has received aggregate payments equaling a 12% internal rate of return (the “IRR”) on the Initial Investment and each Supplemental Investment, if any (the "Hard Cap"): (i) from December 21, 2023 through December 31, 2025, 50% of the amount of royalty payments remaining after all amounts that are due and payable and actually paid by the Company to any licensor or sublicensee on the royalty payments generated and received by the Company on net sales of XACIATO by Organon have been deducted (the “Net Royalty Payments”), (ii) from January 1, 2026 through December 31, 2029, 75% of the Net Royalty Payments, and (iii) from December 21, 2023 through December 31, 2029, 10% of the amount of milestone payments remaining after all amounts that are due and payable and actually paid by the Company to any licensor or sublicensee on the milestone payments generated and received by the Company on net sales of XACIATO by Organon have been deducted. After December 31, 2029, the Company will be required to make certain additional payments to UiE to the extent UiE has not received payments equaling the Hard Cap by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if UiE has not received payments equaling the Hard Cap by December 31, 2035 and the Company has other sources of assets or income besides XACIATO sufficient to complete such payments, the Company has agreed to pay UiE quarterly payments evenly divided over a two-year term, such that UiE will have obtained the IRR, taking into account all other payments received by UiE from the Company under the Royalty Interest Agreement. UiE’s right to receive payments will terminate when UiE has received payments in an amount equal to the Hard Cap.

The Company evaluated the terms of the Royalty Interest Agreement and concluded that the features of the Royalty Interest Agreement were similar to those of a debt instrument. As a result, the Company applied the debt recognition guidance under ASC 470, Debt, and recorded the Initial Investment as a liability related to the sale of future royalties (“Royalty Obligation”) on the Company's 2023 consolidated balance sheet, which will be amortized under the effective interest method over the estimated term of the Royalty Interest Agreement. If the Company elects to receive additional Supplemental Investments, such additional Supplemental Investments will also be recorded as a liability related to the sale of future royalties when they are received and amortized under the interest method over the estimated remaining term of the Royalty Interest Agreement. In addition, in accordance with ASC 470, Debt, the Company will account for any royalties received in the future as non-cash royalty revenue in the consolidated statements of operations as a reduction to the debt balance.

As royalties and milestone payments are received by or on behalf of the Company from Organon and the Company subsequently pays or causes to be paid the amounts due to UiE in respect thereof in accordance with the Royalty Interest Agreement, the Royalty Obligation will be effectively repaid during the term of the Royalty Interest Agreement. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future payments to UiE during the term of the Royalty Interest Agreement.

At execution of the Royalty Interest Agreement, the Company’s estimate of this total interest expense resulted in an effective annual interest rate of approximately 22.48%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the royalty period. The Company will periodically assess the estimated amounts due and payable to UiE and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect XACIATO's commercial success, and therefore the amount and timing of the Company's payments to UiE, and correspondingly, the amount of interest expense recorded by the Company, most of which are not within the Company’s control. Such factors include, but are not limited to, the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product; timely and adequate commercial supply of the finished product and its components; perceived superiority of its cure rates compared to other available treatments; patient satisfaction and willingness to use it again and refer it to others; price pressure given the high level of generic treatments and changes in health care laws and regulations; adequate coverage, pricing and reimbursement from third-party payors; and approval of new entrants, including alternative, non-antibiotic treatment options. These factors could result in increases or decreases to both royalty revenues and interest expense.

Warrants

In connection with entering into the Royalty Interest Agreement, the Company issued to UiE a warrant (the “Initial Royalty Warrant”) to purchase up to 422,804 shares of the Company’s common stock. In addition, for every $1,000,000 of Supplemental Investment, the Company will issue a warrant to purchase 84,561 shares of common stock, for an aggregate of warrants to purchase up to 591,927 shares of common stock (collectively the “Additional Royalty Warrants,” and together with the Initial Royalty Warrant, the “Royalty Interest Agreement Warrants”).

The Royalty Interest Agreement Warrants are exercisable, in full or in part, at any time on or prior to the fifth anniversary of their issuance date at an exercise price of $4.10 per share, subject to customary anti-dilution adjustments. The Royalty Interest Agreement Warrants may be exercised for cash, or if at the time of exercise there is no effective registration statement registering for resale the shares underlying the Royalty Interest Agreement Warrants, then in lieu of paying the exercise price in cash, the holders may elect to exercise on a cashless basis.

The Royalty Interest Agreement Warrants were deemed to be equity classified warrants and recorded under additional paid in capital. The fair value of the Initial Royalty Warrant was determined to be $0.8 million (Note 9) and was recorded as a debt discount against the Initial Investment.

The following table shows the activity of the Royalty Obligation since the transaction inception through the period indicated:

	December 31, 2024
Upfront payment from the sale of future royalties	$ 5,000,000
Debt issuance cost	(276,101)
Relative fair value of Initial Royalty Warrant	(834,512)
Royalty payments	(2,189)
Non-cash interest expense and interest payable associated with the sale of future royalties	862,626
Liability related to the sale of future royalties	$ 4,749,824

13. ROYALTY PURCHASE AGREEMENTS

On April 29, 2024, the Company entered into a traditional royalty purchase agreement (the "XACIATO RPA"), and a synthetic royalty purchase agreement, (the "Synthetic RPA and together with the XACIATO RPA, the “Royalty Purchase Agreements”) with XOMA pursuant to which XOMA paid $22.0 million to the Company. In addition, if XOMA receives total payments under the Royalty Purchase Agreements (as described below) equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to the Company for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements (such $11.0 million payments to the Company, the “Contingent Purchase Price Payments”).

Under the Royalty Purchase Agreements, the Company sold, assigned, transferred and conveyed its right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments the Company would otherwise have the right to receive from and after April 1, 2024 under the Company's exclusive license agreement with Organon, based on net sales of XACIATO, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of the Company under its exclusive license agreement with third-party licensors TriLogic and MilanaPharm, and (ii) all payments due and payable and actually paid by or on behalf of the Company under the Royalty Interest Agreement between the Company and UiE (such net amount, the “Purchased Receivables”);

(b) 25% of the potential future $20.0 million payment that the Company would otherwise have the right to receive under the Company's license agreement with Bayer, if Bayer, in its sole discretion, elects to make the license granted thereunder effective following completion of the pivotal clinical trial of Ovaprene; and

(c) a synthetic royalty of 4.0% of the Company's, its affiliates’ and its sublicensees’ future net sales of the Company's investigational product Ovaprene, and 2.0% of the Company's, its affiliates’ and its sublicensees’ future net sales of the Company's investigational product Sildenafil Cream, 3.6%; *provided, however*, that, if XOMA receives total payments under the Royalty Purchase Agreements, net of any Contingent Purchase Price Payments made to the Company, equal to an amount that exceeds $110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (such amounts described in the foregoing clauses (b) and (c), collectively, the “Revenue Participation Right”).

Pursuant to the XACIATO RPA, XOMA, at its sole cost and discretion, may repay in full and retire all of the Company's payment obligations to UiE under the Royalty Interest Agreement. If XOMA does so, no further amounts in respect of the Royalty Interest Agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the XACIATO RPA. As of April 29, 2024, the Company cannot elect to receive any additional funding from UiE under the Royalty Interest Agreement without XOMA’s prior written consent. In connection with the synthetic royalty purchase agreement, the Company granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream.

The $22.0 million the Company received from XOMA, less transaction costs of approximately $1.6 million, was allocated to the XACIATO RPA and recorded as other income on the Company's consolidated statement of operations and comprehensive loss in the second quarter of 2024. See Note 2, Basis of Presentation and Summary of Significant Accounting Policies, for additional information.

14. COMMITMENTS AND CONTINGENCIES

Insurance Financing

In each of July 2024 and 2023, the Company obtained financing for certain director and officer and other insurance premiums. The total premiums, taxes and fees financed each year was approximately $0.6 million with an annual interest rate of approximately 8.0%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreements and the Company assigned to the lender a first priority lien on and a security interest in the financed insurance policies. With respect to the financing obtained in July 2024, the Company will make monthly installment payments through April 20, 2025. With respect to the financing obtained in July 2023, the Company made monthly installment payments through April 20, 2024. The financed amount is recognized as an insurance financing cost included in other current assets and accrued expenses in the Company's consolidated balance sheets. As of December 31, 2024, the Company's remaining obligation for the financing obtained in July 2024 was approximately $0.2 million. As of December 31, 2023, the Company's remaining obligation for the financing obtained in July 2023 was approximately $0.3 million. The Company had no remaining obligations for the financing obtained in July 2023 as of December 31, 2024.

CRADA with NICHD for the Pivotal Phase 3 Study of Ovaprene

In July 2021, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene, or the Ovaprene Phase 3. The Ovaprene Phase 3 is being conducted within NICHD’s Contraceptive Clinical Trials Network with NICHD's contract research organization providing clinical coordination and data collection and management services for the Ovaprene Phase 3. The Company and NICHD each provide medical oversight and final data review and analysis for the Ovaprene Phase 3 and will work together to prepare the final report of the results of the Ovaprene Phase 3. The Company is responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in payments to NICHD to be applied toward the costs of conducting the Ovaprene Phase 3. NICHD is responsible for the other costs related to the conduct of the Ovaprene Phase 3. The Company made aggregate payments of $5.5 million to NICHD, $0.5 million of which was paid in July 2024 and $5.0 million of which was paid in prior years. The Company had no remaining obligation under the CRADA at December 31, 2024.

Legal Proceedings

From time to time, the Company may be involved in various claims arising in the normal course of business. Management is not aware of any material claims, disputes or unsettled matters that would have a material adverse effect on the Company’s results of operations, liquidity or financial position that the Company has not adequately provided for in the accompanying consolidated financial statements.

Employment Agreements

Certain employees of the Company are entitled to payments if their employment is terminated by the Company without cause, if they resign for good reason, if their employment agreements are not renewed, or if their employment is terminated by the Company without cause or if they resign for good reason, in each case, within three months prior to or 12 months following a change in control of the Company. Upon termination by the Company without cause, if they resign for good reason, if their employment agreements are not renewed, such executives are entitled to receive a payment of an amount equal to either six or twelve months of base salary and to receive continuing health benefits coverage for periods equal to either six or twelve months following the termination of employment or until such officer is covered under a separate plan from another employer. If their employment is terminated by the Company without cause or if they resign for good reason, in each case, within three months prior to or 12 months following a change in control of the Company, such executives will be entitled to receive a payment of an amount equal to either nine or eighteen months of base salary and target bonus and to receive continuing health benefits coverage for periods ranging between nine and eighteen months following the termination of employment. In addition,

upon a change in control of the Company, each officer's outstanding unvested options will fully vest and accelerate subject to the conditions outlined in such officer's employment agreement.

Related-Party Agreement

On January 26, 2024, the Company entered into a consulting agreement with its former Chief Financial Officer to assist in transition matters subsequent to her retirement. Pursuant to the agreement, for a nine month period commencing on January 26, 2024, the Company paid its former Chief Financial Officer $31,667 per month and reimbursed her up to $500 per month for her health insurance premiums.

Employee Benefit – 401(k) Plan

The Company has a 401(k) retirement plan, or the 401(k) Plan, covering all qualified employees. The 401(k) Plan allows each participant to contribute a portion of their base wages up to an amount not to exceed an annual statutory maximum. The 401(k) Plan includes a Safe Harbor Plan that provides a Company match up to 4% of each participant's cash compensation. The Company made matching contributions of approximately $0.2 million and $0.2 million during the years ended December 31, 2024 and 2023, respectively.

15. GRANT AWARDS

October 2024 Grant Award

In October 2024, the Company entered into a subaward agreement with National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell (the "CMF") under which the Company is entitled to receive funding of up to $10.0 million in milestone-based payments subject to the Company's achievement over an approximately 24-month period of specified research activities and objectives relating to the advancement of the Company's DARE-HPV development program, including commencement of a Phase 2 clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for the clearance of high-risk HPV infection in women. The subaward agreement was the result of the Company's selection by an agency within the U.S. Department of Health and Human Services. The CMF is a consortium management firm that received funding from the federal agency for the subaward agreement.

The Company receives funding in advance and tracks and reports eligible expenses incurred to the federal agency. The Company is required to apply the funds it receives solely toward direct costs for the funded project, other than approximately 22% of such funds, which it may apply toward general overhead and administrative expenses that support the entire operations of the Company. Funds received that have not been spent are recorded as cash and cash equivalents and as a deferred grant funding liability in the Company's consolidated balance sheets. The deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. The Company must track expenses incurred under the award and submit a detailed accounting of such expenses. Through December 31, 2024, the Company received one payment of $1.0 million under this award. The Company recorded credits to research and development expense of approximately $0.4 million for costs related to this award for the year ended December 31, 2024. As of December 31, 2024, the Company has recorded approximately $0.6 million of deferred grant funding liability in the Company's consolidated balance sheets.

NICHD and NIH Non-Dilutive Grant Funding

The Company has received notices of awards and non-dilutive grant funding from the NICHD and the National Institutes of Health, or NIH, to support the development of several of its product candidates. The NICHD and NIH issue notices of awards to the Company for a specified amount, and the Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment. If the Company receives payments under the award, the amounts of such payments are recognized in the statements of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

DARE-HPV

In December 2024, the Company received a notice of award from the National Institute of Allergy and Infectious Diseases (NIAID), a component of the NIH, that the Company was awarded a $1.0 million grant in support of non-clinical activities for the development of DARE-HPV for an initial project year of December 2024 through November 2025, and that an additional $1.0 million was recommended for the subsequent project year, subject to the availability of funds and satisfactory progress of the project, as determined by NIAID. The Company recorded no credits to research and development expense for costs related to the NIH award for the year ended December 31, 2024 and recorded no receivable at December 31, 2024.

DARE-PTB1

In August 2020, the Company received a notice of award from NICHD to support the development of DARE-PTB1. The award of approximately $0.3 million was used for what was referred to as the "Phase I" segment of the project outlined in the Company's grant application, which ended in July 2023. The Company received aggregate reimbursements under the award of approximately $0.2 million during the grant period which ended in July 2023. No further funds are available under this award for the Phase I segment.

In December 2023, the Company received a notice of award of approximately $2.0 million for the "Phase II" segment of the project. The Company recorded credits to research and development expense for costs related to the NICHD award of approximately $0.7 million for the year ended December 31, 2024. The Company recorded a receivable of approximately $0.1 million at December 31, 2024 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

DARE-LARC1

In September 2021, the Company received a notice of award from NICHD to support the development of DARE-LARC1. The award in the amount of approximately $0.3 million was used to explore device insertion and removal in nonclinical studies.

The Company recorded credits to research and development expense of approximately $32,000 for costs related to the NICHD award for the year ended December 31, 2023. The Company received aggregate reimbursements under the NICHD award of approximately $0.3 million during the grant period, which ended in June 2023. No further funds are available under this award.

DARE-204 and DARE-214

In May 2022, the Company received a notice of award from NICHD of approximately $0.2 million to support end-user research to better understand women's preferences for a long-acting injectable contraceptive method. The findings from the research will inform the Company's target product profile and guide its development priorities for DARE-204 and DARE-214.

The Company recorded credits to research and development expense of approximately $0.1 million for costs related to the NICHD award for the year ended December 31, 2023. The Company received aggregate reimbursements under the NICHD award of approximately $0.2 million during the grant period, which ended in September 2023. No further funds are available under this award.

DARE-PTB2

In July 2023, the Company received a notice of award from NICHD of approximately $0.4 million to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds will support activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida, which are to occur over a 12-month period.

The Company recorded credits to research and development expense of approximately $0.3 million and $0.1 million for costs related to the NICHD award for the year ended December 31, 2024 and 2023, respectively. The Company received aggregate reimbursements under the NICHD award of approximately $0.4 million during the grant period, which ended in July 2024. No further funds are available under this award.

Other Non-Dilutive Grant Funding

As described below, the Company has received substantial funding under grant agreements it entered into with the Gates Foundation, or the Foundation. The Company is required to apply the funds it receives under the agreements solely toward direct costs for the applicable funded projects, other than approximately 5%-15% of such funds, which it may apply toward general overhead and administrative expenses that support the entire operations of

the Company. The Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Funds received that have not been spent are recorded as cash and cash equivalents and as a deferred grant funding liability in the Company's consolidated balance sheets. The deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. The grant agreements include the Foundation's standard discretionary termination provisions. Any grant funds that have not been used or committed to the funded project must be returned promptly to the Foundation upon expiration or termination of the agreement.

2024 Contraceptive Product Candidate Grant Agreement

In November 2024, the Company entered into a grant agreement with the Foundation under which the Company was awarded a new grant of up to approximately $10.7 million to support (i) expansion of the number of study sites in the ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in low- and middle-income country settings who need or would prefer to use such a product to avoid an unplanned pregnancy. An initial payment of approximately $5.4 million was made to the Company in November 2024. Additional payments are contingent upon the Company's achievement of specified development and reporting milestones during the term of the grant agreement, which extends through October 2026. The Company will track and report eligible expenses incurred to the Foundation.

The Company recorded credits to research and development expense of approximately $0.2 million for costs related to this award for the year ended December 31, 2024. As of December 31, 2024, the Company has recorded approximately $5.2 million of deferred grant funding liability related to this award in the Company's consolidated balance sheets.

2024 Biotherapeutic Product Grant Agreement

In January 2024, the Company entered into an agreement with the Foundation under which the Company was awarded $750,000 to fund activities related to bacteria-based live biotherapeutic product development. The Company received the full amount of the award in January 2024.

The Company recorded credits to research and development expense of approximately $0.7 million for costs related to this award for the year ended December 31, 2024. As of December 31, 2024, the Company has recorded approximately $39,000 of deferred grant funding liability related to this award in the Company's consolidated balance sheets.

2021 DARE-LARC1 Grant Agreement

In June 2021, the Company entered into an agreement with the Foundation under which the Company was awarded up to approximately $49.0 million to support the development of DARE-LARC1. The agreement supports technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 through nonclinical proof-of-principle studies and other IND-enabling work to allow for the submission of an IND application with the FDA, approval of which will be required to commence testing in humans.

As of December 31, 2024, the Company has received a cumulative total of approximately $31.8 million in non-dilutive funding under the agreement, including $4.5 million during 2023 and $3.5 million during 2024. Additional payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones. The Company recorded credits to research and development expense of approximately $6.2 million and $8.7 million for costs related to this award for the year ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company recorded approximately $10.8 million of deferred grant funding liability related to this award in the Company's consolidated balance sheets.

2022 DARE-LBT Grant Agreement

In November 2022, the Company entered into an agreement with the Foundation under which the Company was awarded $585,000 to support the development of DARE-LBT over the period of November 11, 2022 to February 29, 2024.

The Company received the full amount of the award in November 2022. The Company recorded credits to research and development expense of approximately $0.2 million and $0.3 million for costs related to this award for the year ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company had no deferred grant funding liability related to this award in the Company's consolidated balance sheets.

16. SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), in deciding how to allocate resources and in assessing performance. The Company and the Company's chief operating decision maker view the Company's operations and manage its business in one operating segment, which is the business of identifying, developing and commercializing pharmaceutical products that target unmet needs in women's health. The CODM, who is the chief executive officer ("CEO"), manages and allocates resources to the operations of the Company on a consolidated basis. The Company's measure of segment profit or loss is net loss. Managing and allocating resources on a consolidated basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The CODM does not review assets in evaluating the results of the Company, and therefore, such information is not presented. In addition, substantially all of the Company's revenue was generated in the United States and substantially all of the Company's long-lived assets reside in the United States.

The following table summarizes the segment's financial information including the Company's significant segment expenses:

	Year Ended December 31,	
	2024	2023
Revenue:		
License fee revenue	$ —	$ 1,000,000
Milestone revenue	—	1,800,000
Royalty revenue	9,784	7,885
Total revenue	9,784	2,807,885
Segment operating expenses:		
Research and development:		
Direct program costs:		
Ovaprene	8,518,495	3,762,611
Sildenafil Cream, 3.6%	2,361,052	7,746,264
Other advanced clinical stage programs	1,321,888	3,498,955
Phase 1 and Phase 1-ready clinical stage programs	761,721	2,912,857
Preclinical stage programs	4,233,762	7,432,439
Other development programs	27,542	189,706
Contra-R&D expenses	(7,685,533)	(8,965,347)
Total research and development direct program costs	9,538,927	16,577,485
Indirect costs:		
Personnel-related (including stock compensation)	5,611,057	5,566,016
Other indirect costs	254,772	384,289
Contra R&D expenses	(1,199,548)	(989,716)
Total research and development indirect costs	4,666,281	4,960,589
General and administrative	9,156,061	12,109,691
Other operating expenses	100,000	100,000
Total segment operating expenses	23,461,269	33,747,765
Loss from operations	(23,451,485)	(30,939,880)
Sale of royalty and milestone rights, net	20,379,376	—
Interest expense	857,364	35,109
Interest income	(539,743)	(813,278)
Other income (expense), net	663,869	(320)
Net loss	$ (4,053,599)	$ (30,161,391)

17. SUBSEQUENT EVENTS

Noncompliance with Nasdaq's Minimum Market Value of Listed Securities Requirement

On August 12, 2024, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") notifying it that it did not meet the requirement in Nasdaq Listing Rule 5550(b)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(2) requires a company listed on Nasdaq to maintain a minimum market value of listed securities of $35.0 million (the "Minimum MVLS Rule"). The Company was provided an initial period of 180 calendar days, or until February 10, 2025, to regain compliance with the Minimum MVLS Rule.

On February 13, 2025, Nasdaq's Listing Qualifications Department notified the Company that because it did not regain compliance with the Minimum MVLS Rule by February 10, 2025, its common stock is subject to delisting from Nasdaq unless the Company timely requests a hearing before the Nasdaq Hearing Panel (the "Panel").

On February 20, 2025, the Company requested a hearing before the Panel, which request stayed the delisting of its common stock pending the decision of the Panel following the hearing and the expiration of any extension period that may be granted by the Panel. The hearing occurred on March 25, 2025. Pursuant to published Nasdaq guidance, the Panel typically issues it decision within 30 days of the hearing.

There can be no assurance that the Panel will grant the Company any extension period within which to regain compliance with the Minimum MVLS Rule, or if any extension period is granted, that the Company will regain compliance with the Minimum MVLS Rule within such extension period, or that the Company will be successful in otherwise maintaining the listing of our common stock on The Nasdaq Capital Market.

Exhibit 10.10

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this "Agreement") is made as August 12, 2023 ("Effective Date"), by and between Douglas Pharmaceuticals Limited, a New Zealand company, ("Douglas") and Daré Bioscience, Inc., a Delaware corporation ("Licensee"), each referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Douglas owns or has the exclusive rights to certain patent rights and owns or has non-exclusive rights to certain technical information, in each case relating to a Lopinavir:Ritonavir combination soft gel vaginal insert for treating cervical intraepithelial neoplasia ("CIN"), and desires to grant licenses of those patent rights and technical information to Licensee;

WHEREAS, Licensee desires to license such patent rights and technical information and has the capability to commercially develop, manufacture, distribute and use Products (as defined below) and Processes (as defined below).

NOW THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. CERTAIN DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings, unless the context requires otherwise.

1.1 "Affiliate" with respect to either Party and Manchester means any corporation or other legal entity other than that Party or Manchester, as applicable, in whatever country organized, controlling, controlled by or under common control with that Party or Manchester, as applicable. The term "control" shall mean (i) the direct or indirect ownership of fifty percent (50%) or more of the voting securities having the right to elect directors, or (ii) the power, direct or indirect, to elect or appoint fifty percent (50%) or more of the directors, or to cause direction of management and policies, whether through the ownership of voting securities, by contract or otherwise.

1.2 "Ancillary Agreements" mean the development services agreement, clinical product supply agreement, commercial supply agreement and other agreements that may be entered into between the Parties pursuant to Section 11.5.

1.3 "Average Daily Trading Volume" means the average daily trading volume of the common stock of Registrant for [***].

1.4 "Clinical Data" means all data and information set forth on Exhibit D.

1.5 "Clinical Trial" shall mean a Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, or post-Governmental Approval human clinical trial.

1.6 "Combination Product"

(a) A Product or Process that is [***].

(b) [***].

1.7 "Commercially Reasonable Efforts" shall mean with respect to the efforts to be expended by Licensee [***].

1.8 "Cover" shall mean, with respect to a particular subject matter at issue and a relevant Valid Claim, as applicable, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of such Valid Claim. "Covering" and "Covered" will have correlative meanings.

1.9 "Development Plan" shall mean the development plan provided by Licensee to Douglas that provides the activities, and the associated timelines of when such activities shall be conducted (including in detail the activities that shall be conducted in the calendar year following the submission of such Development Plan to Douglas), in order to develop a Product for commercialization.

1.10 "Distributor" shall mean any third-party entity to whom Licensee, an Affiliate of Licensee or a Sublicensee has granted, express or implied, the right to distribute any Product or Process pursuant to Section 2.1(b)(iii).

1.11 "Douglas Inventions" shall mean any and all copyrights, patents, trade secret rights, and other intellectual property rights that may be conceived, made, authored, discovered, reduced to practice or otherwise created by Douglas solely or jointly with third parties.

1.12 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended and the regulations thereunder.

1.13 "Exchange Act Reports" shall mean all reports required to be filed pursuant to Sections 13(a), 13(e), 14 and 15(d) of the Exchange Act during the preceding 12 months with the Securities and Exchange Commission by Registrant.

1.14 "FDA" means the United States Food and Drug Administration and any successor governmental authority having substantially the same function.

1.15 "First Commercial Sale" shall mean the initial Sale by Licensee or an Affiliate of Licensee or a Sublicensee in an arms-length transaction to a third party in the License Territory after obtaining necessary marketing and pricing approval, to the extent both are required, from regulatory authorities of a specific Product or Process, but excluding any Sale of a reasonable quantity of Products for clinical trial purposes or marketing samples.

1.16 "Governmental Approval" shall mean, with respect to a Product in the License Territory, the approval, clearance, license, registration, or authorization (including but not limited to emergency use authorization) by the FDA for the commercialization of such Product in the License Territory.

1.17 "Governmental Authority" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasigovernmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, representative, organization, unit, body or entity and any court or other tribunal); (d) multinational or supranational organization or body; or (e) individual, entity, or body, including any court, exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.18 "Improvement" shall mean any inventions, discoveries, improvements (whether patentable or not), information, and data, conceived, made, authored, discovered, reduced to practice or otherwise created at any time during the term of this Agreement whether by Douglas (including pursuant to a development services agreement entered into by the Parties), Licensee, or jointly by Douglas and Licensee, and which would infringe an issued or pending claim within the Patent Rights or other intellectual property rights owned or controlled by Douglas.

1.19 "Law" or "Laws" shall mean all applicable laws, statutes, rules, regulations, ordinances, and other pronouncements having the binding effect of law of any Governmental Authority.

1.20 "License Field" shall mean all human pharmaceutical, therapeutic, preventative and palliative uses, including, treatment or prevention of all indications for women in female reproductive health, including but not limited to, cancers or benign proliferative disorders of the vagina or cervix, such as cervical intraepithelial neoplasia, anal intraepithelial neoplasia, vulvar intraepithelial neoplasia, and HSV infections (only in so far as they relate to women in female reproductive health), and shall not include any other field not specifically set forth herein.

1.21 "License Territory" shall mean the Unites States of America and its territories and possessions.

1.22 "Licensed IP" means, collectively, Douglas' interest in Improvements, Douglas' interest in Non-Product Inventions, the Patent Rights, and Technological Information.

1.23 "Licensee Inventions" shall mean any and all copyrights, patents, trade secret rights, and other intellectual property rights other than Improvements that may be conceived, made, authored, discovered, reduced to practice or otherwise created by Licensee solely or jointly with third parties (other than Douglas).

1.24 "Licensee Process" shall mean any process, method of use or service, whether patented or not, other than a Process, developed or licensed by Licensee.

1.25 "Licensee Product" shall mean any article, device or composition, whether patented or not, other than a Product, developed or licensed by Licensee.

1.26 "Listed Product Bridging Strategy" refers to [***].

1.27 "Manchester" means the University of Manchester, a Royal Charter corporation registered in England under number RC 00797, of Oxford Road, Manchester, M13 9PL, England.

1.28 "Manchester Licensed IP" means those Patent Rights owned by Manchester and licensed to Douglas under the Underlying Agreement.

1.29 "Net Sales" shall be calculated as set forth in this Section 1.29, all in accordance with U.S. Generally Accepted Accounting Principles, applied on a consistent basis. Subject to the conditions set forth below, "Net Sales" shall mean the gross amount received by Licensee and its Affiliates for or on account of Sales of Products and Processes in the License Territory following First Commercial Sale in the License Territory (including any cash amounts plus the fair market value of any other forms of consideration), less the following amounts [***].

[***]

1.30 "Non-Product Invention" shall mean any invention (other than Improvements) conceived, made, authored, discovered, reduced to practice or otherwise created jointly by Douglas and Licensee in the course of this Agreement.

1.31 "Patent Rights" shall mean all patents and patent applications that are listed on Exhibit A, including all provisionals, substitutions, continuations, continuations-in-part, divisionals, supplementary protection certificates, inventor's certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations, patents of addition thereof, and PCTs to all of the foregoing. For the avoidance of any doubt, Patent Rights are limited by the License Field and the License Territory.

1.32 "Phase 1 Clinical Trial" shall mean, as to a specific Product or Process, in connection with obtaining regulatory approval in the United States, the first clinical study conducted in humans to obtain preliminary information on a Product's safety, tolerability, pharmacodynamic activity, pharmacokinetics, drug metabolism and mechanism of action, as well as early evidence of effectiveness if possible, as described more fully in 21 C.F.R. § 312.21(a), provided, [***]. The Product or Process can be administered to patients as a single agent or in combination with other investigational or marketed agents.

1.33 "Phase 2 Clinical Trial" shall mean, as to a specific Product or Process, in connection with obtaining regulatory approval in the United States, a clinical study in humans designed with the principal purpose of determining initial efficacy and dosing of such Product or Process in patients for the indication(s) being studied, as described more fully in 21 C.F.R. § 312.21(b), including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. §312.21(a) and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. §312.21(b) or otherwise to enable a Phase 3 Clinical Trial (e.g., a Phase 1/2 Clinical Trial), provided, [***]. The Product or Process can be administered to patients as a single agent or in combination with other investigational or marketed agents.

1.34 "Phase 3 Clinical Trial" shall mean, as to a specific Product or Process, in connection with obtaining regulatory approval in the United States, a clinical study in humans with a defined dose or set of defined doses of such Product or Process, after successful completion of one or more Phase 2 Clinical Trials, of the efficacy and safety of such Product or Process which is prospectively designed to demonstrate statistically whether such Product is effective and safe for use in a particular indication in a manner sufficient to file an application to obtain marketing approval to market and sell that Product or Process in the United States, as described more fully in 21 C.F.R. § 312.21(c). The Product or Process can be administered to patients as a single agent or in combination with other investigational or marketed agents.

1.35 "Process" shall mean any process, method of use or service, the performance of which, in whole or in part:

(a) is Covered by one or more Valid Claims of Patent Rights; or

(b) incorporates or is based upon Improvements, Non-Product Inventions, or Technological Information.

1.36 "Product" shall mean any article, device or composition, the manufacture, import, use, or sale of which, in whole or in part:

(a) is Covered by one or more Valid Claims of Patent Rights; or

(b) incorporates or is based upon Improvements, Non-Product Inventions, or Technological Information.

1.37 "Prohibited Activity" means any of the following: (a) pornography; (b) the development, production, promotion, marketing and/or sale of tobacco or products containing or derived from tobacco; (c) the principal activity of the manufacture or sale of arms or weapons designed to inflict harm to human beings; (d) directly deriving revenue from thermal coal or oil sands; and (e) such other industries or activities as the Parties and Manchester may from time to time unanimously agree and "Prohibited Activities" shall be construed accordingly.

1.38 "Registrant" shall mean Daré Bioscience, Inc. or any successor with a class of equity securities registered under the Exchange Act.

1.39 "Reporting Period" shall mean each three-month period ending March 31, June 30, September 30 and December 31.

1.40 "Royalty Term" shall mean, in the License Territory, on a Product-by-Product and Process-by-Process basis, the period of time beginning with the First Commercial Sale in the License Territory and ending upon the latest to occur of (a) expiration of the last-to-expire Valid Claim in the License Territory, or (b) ten (10) years from the date of First Commercial Sale in the License Territory.

1.41 "Sell" (and "Sale" and "Sold" as the case may be) shall mean to sell, have sold or offer to sell, to lease or have leased, to import or have imported, in each case for valuable consideration (in the form of cash or otherwise) a Product or Process, or otherwise to transfer or have transferred a Product or Process for valuable consideration (in the form of cash or otherwise), and further in the case of a Process, to use or perform such Process for the benefit of a third party.

1.42 "Share Market Value" shall mean [***].

1.43 "Stock Consideration" shall mean a number of shares of common stock of Registrant equal to [***].

1.44 References to a "successful" Clinical Trial shall mean the Product or Process meets the primary endpoint set forth in the Clinical Trial protocol, unless the Parties agree in writing on a different definition of success.

1.45 "Sublicense Income" shall mean consideration in any form received by Licensee and/or Licensee's Affiliate(s) directly in consideration for and directly attributable to a grant of a Sublicense under the license grant in Section 2.1 to the Licensed IP (regardless of whether such grantee is a Sublicensee) to make, have made, use, have used, Sell or have Sold Products or Processes. Sublicense Income shall include [***].

Sublicense Income shall not include [***].

1.46 "Sublicensee" shall mean any sublicensee of rights granted under Section 2.2 other than an Affiliate of Licensee. For purposes of this Agreement, neither a Distributor of a Product or Process nor a contract manufacturer shall be included in the definition of Sublicensee unless such Distributor or contract manufacturer (i) is granted any right to make, have made, use or have used Products or Processes in accordance with Section 2.2, or (ii) has agreed to pay to Licensee or its Affiliate(s) royalties on such Distributor's or contractor manufacturer's sales of Products or Processes, in which case such Distributor or contract manufacturer shall be a Sublicensee for all purposes of this Agreement. For clarity, a clinic that is granted the right to use or have used Products or Processes to treat patients shall not be considered a Sublicensee if Licensee or its Affiliate(s) do not receive royalties or other payments (other than the price paid for the Product or Process) related to such clinic's use of Products or Processes.

1.47 "Technological Information" shall mean proprietary discoveries, know-how and technical information known, licensed, owned, controlled or developed by Douglas or its Affiliates related to pharmaceutical compositions comprising lopinavir and ritonavir for all indications as of the Effective Date, including for the sake of clarity, Technological Information licensed to Douglas pursuant to the Underlying Agreement and any subsequent improvements thereto, all as set forth on Exhibit B attached hereto; provided, however, that Technological Information shall not include the proprietary discoveries, know-how and technical information related to the development and manufacturing services that will be provided by Douglas pursuant to the Ancillary Agreements.

1.48 "Trading Day" shall mean a day on which the principal Trading Market is open for trading.

1.49 "Trading Market" shall mean any of the following markets or exchanges on which the common stock of Registrant is listed or quoted for trading on the date in question: the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, the NYSE MKT, the OTCQB or OTCQX (or any successors to any of the foregoing).

1.50 "Underlying Agreement" shall mean that certain License Agreement, [***], by and between Douglas and Manchester, as amended, and as may be amended or restated from time to time.

1.51 "Valid Claim" shall mean a claim in an issued, unexpired patent or in a pending patent application within Patent Rights that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction without the possibility of re-filing of the application or appeal, (b) has not been revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) is not lost through an interference proceeding. Notwithstanding the foregoing, [***].

1.52 "VWAP" shall mean, for any date, the daily volume weighted average price of the common stock for such date (or the nearest preceding date) on the Trading Market on which the common stock of Registrant is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:00 p.m. (New York City time)).

2. LICENSE

2.1 Grant of License.

(a) Subject to the terms of this Agreement and the retained rights of Manchester under Clause 2.6 of the Underlying Agreement, Douglas hereby grants to Licensee in the License Field in the License Territory:

(i) an exclusive, royalty-bearing license under the Patent Rights, Improvements and Non-Product Inventions to make, have made, use, have used, sell, have sold, offer to sell, import and have imported the Products;

(ii) an exclusive, royalty-bearing license under the Patent Rights, Improvements and Non-Product Inventions to perform, use and have used the Processes to make, have made, use, have used, sell, have sold, offer to sell, import and have imported the Products;

(iii) a non-exclusive, royalty-bearing license to use the Technological Information to make, have made, use, have used, sell, have sold, offer to sell, import, and have imported Products; and.

(iv) a non-exclusive, royalty bearing license to use the Technological Information to perform, use and have used the Processes to make, have made, use, have used, sell have sold, offer to sell, import and have imported the Products.

(b) The license granted in Section 2.1(a) includes:

(i) The right to grant to the final purchaser, user or consumer of Products the right to use such purchased Products within the License Field and License Territory;

(ii) the right to engage third parties to manufacture Products for sale to Licensee and its Affiliates and Sublicensees; and

(iii) the right to grant a Distributor the right to sell, have sold, offer to sell, use, have used, import and have imported (but not to make and have made) such Products and/or Processes for its own benefit in a manner consistent with this Agreement within the License Field and License Territory.

Licensee acknowledges that this Agreement does not confer by implication, estoppel, or otherwise, any license or rights to any intellectual property rights, whether belonging to Douglas or any third party, other than those rights expressly stated herein.

(c) Licensee may permit its Affiliates to exercise all rights granted to Licensee hereunder such that such Affiliates shall have the same license rights granted to Licensee hereunder provided that Licensee shall secure in advance from each such Affiliate its written agreement to comply with all appropriate covenants, obligations and rights under this Agreement so that such Affiliate is subject to, and Licensee can comply with, all of Licensee's covenants and obligations to Douglas under this Agreement. Licensee shall be responsible for any failure of any of its Affiliates to comply with this Agreement.

(d) Under no circumstances shall Licensee use and/or permit, facilitate or enable the use of any of the Manchester Licensed IP directly or indirectly in connection with any of the Prohibited Activities.

2.2 Sublicenses.

(a) Douglas grants to Licensee the right to grant sublicenses under the rights granted in Section 2.1(a) to Sublicensees (each, a "Sublicense") subject to the terms and conditions of this Agreement and specifically this Section 2.2. The term Sublicense shall include any grant of rights under the license by a Sublicensee to any downstream third party, such downstream third party shall also be considered a Sublicensee for purposes of this Agreement.

(b) Each Sublicense shall be consistent with and comply with all relevant terms of this Agreement and the Underlying Agreement, and shall incorporate terms and conditions sufficient to enable Licensee to comply with this Agreement. [***] Upon termination of this Agreement or any license granted hereunder for any reason, any Sublicenses shall be addressed in accordance with Section 10.7.

(c) All Sublicenses will (1) be issued in writing, (2) to the extent applicable, include all of the rights of Douglas and require the performance of obligations due to Douglas contained in this Agreement and (3) include [***].

Any Sublicense that does not include all of the terms and conditions set forth in Section 2.2(c) or which is not issued in accordance with the terms and conditions set forth in this Section 2.2, shall be voidable [***], unless such Sublicense is amended to conform with all of the terms and conditions set forth in this Section 2.2(c) [***].

(d) Douglas' receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Douglas or obligation of Licensee under this Agreement.

(e) Licensee shall provide [***] Sublicense Development Report [***] during the term of this Agreement ("SDR Report").

2.3 Retained Rights; Requirements. Any and all Sublicenses and other licenses granted hereunder are subject to the retained rights and requirements specified in Clause 2.6 of the Underlying Agreement, namely that Manchester reserves the rights for its employees and students to use the Manchester Licensed IP in any way for any bona fide research or teaching purposes and to sublicense such rights to Manchester's Affiliates for any bona fide research or teaching purposes.

2.4 No Implied License. Each Party acknowledges that the rights and licenses granted in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to any know-how, patent or other intellectual property rights that are not specifically granted herein are reserved to the owner thereof.

2.5 Technology Transfer and Regulatory Support.

(a) Initial Technology Transfer. Douglas shall, [***], at Douglas's cost, fully disclose and deliver to Licensee the following: (i) all Technological Information currently in Douglas' possession or control, in a form and format as reasonably agreed by the Parties and (ii) all clinical data, regulatory materials, and any other data, information, materials or inventory relevant to the Products and Processes, in each case currently in Douglas' possession or control.

(b) Douglas acknowledges that Licensee's timely access to Clinical Data will help Licensee successfully and efficiently develop and commercialize Products and Processes in the License Field in the License Territory. Douglas shall use its commercially reasonable efforts to require its licensees of the Products and Processes in all countries and jurisdictions outside of the License Territory to share Clinical Data owned or controlled by such licensees with Licensee on a timely basis. Douglas shall require its licensees of the Products and Processes in all countries and

jurisdictions outside of the License Territory to enter into a Safety Data Exchange Agreement ("SDEA") and share Clinical Data with Douglas pursuant to the terms of the SDEA.

(c) Licensee shall share clinical data owned or controlled by Licensee from Clinical Trials of Licensed Products and Licensed Processes in the License Territory ("Licensee Clinical Data") with Douglas and Licensee shall grant Douglas a nonexclusive license, with the right of sublicense, to use Licensee Clinical Data in the development, commercialization and exploitation of Products and Processes outside of the License Field and outside of the License Territory; provided that, prior to such disclosure and license the Parties have agreed in writing [***] and on such additional commercially reasonable terms as they may agree.

(d) Douglas shall provide Licensee with such documentation and support as may be requested by Licensee from time to time as is reasonably necessary or desirable to prepare, file, obtain or maintain any regulatory filing and/or regulatory approval for Products or Processes throughout the License Territory, including without limitation providing information relating to the chemistry, manufacturing and control section of any Douglas regulatory filing, pursuant to the terms of a development services agreement entered into after the Effective Date and referenced in Section 11.5. For the avoidance of doubt, all Technological Information, clinical data, regulatory materials, and any other data, information, materials and inventory relevant to the Products and Processes transferred to Licensee pursuant to Section 2.5(a) of this Agreement shall not be subject to or addressed by such development services agreement referenced herein.

2.6 Pharmacovigilance Agreement; Global Safety Database. The Parties shall enter into a pharmacovigilance agreement promptly following the Effective Date providing for terms pursuant to which (i) Douglas shall establish, hold and maintain (at Douglas's sole cost and expense) the global safety database for Licensed Products, and (ii) Licensee shall timely provide Douglas with information in the possession and control of Licensee as necessary for Douglas to comply with its pharmacovigilance responsibilities outside the Territory, and Douglas shall timely provide Licensee with information in the possession and control of Douglas as necessary for Licensee to comply with its pharmacovigilance responsibilities within the Territory, including in each case, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign regulatory authorities under corresponding applicable Law outside the United States) from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies and commercial experiences with a Licensed Product, [***].

3. DUE DILIGENCE OBLIGATIONS

3.1 Diligence Requirements. Licensee shall use, and shall cause its Affiliates and Sublicensees, as applicable, to use, Commercially Reasonable Efforts to develop and make available to the public at least one Product or Processes in the License Territory in the License Field. Such efforts shall include achieving the requirements set forth in the table below by the dates specified in the table below:

	Diligence Requirements	**Time for Completion**
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]

Achievement of the foregoing objectives shall be deemed to satisfy Licensee's obligations to use Commercially Reasonable Efforts under this Section 3.1.

3.2 Diligence Failures. If Licensee believes it may not achieve a diligence requirement in Section 3.1, it may notify Douglas [***], in which case the Parties shall work together in good faith to extend the applicable time for

completion, [***]. In the event Licensee has materially failed to fulfill any of its obligations under Section 3.1 (as may be adjusted under this Section 3.2), and subject to resolution under the dispute resolution provisions of Section 12.13 and failure to cure as permitted in Section 10.4, then Douglas may treat such material failure as a material breach and may terminate this Agreement and/or any license granted to Licensee hereunder in accordance with Section 10.4. Douglas and Licensee are free to renegotiate the diligence requirements in good faith and memorialize any changes to the due diligence requirements in an amendment to the Agreement.

3.3 Product Development.

(a) Licensee or its Sublicensees shall be responsible for all costs in connection with obtaining regulatory approval of the Products or Processes in the United States. Other than the Technological Information, the costs to be paid for proprietary discoveries, know-how and technical information related to the development and manufacturing services shall be set forth in the Ancillary Agreements.

(b) Licensee shall provide the initial Development Plan to Douglas [***] and such initial Development Plan shall be incorporated as an exhibit to this Agreement. [***], Licensee shall submit an updated Development Plan for all Products or Processes, [***].

3.4 Progress Reports. So long as Licensee continues to develop Products or Processes, Licensee shall submit to Douglas [***] a progress report (each, a "Progress Report") covering Licensee's (and any Affiliates' and Sublicensees') activities related to the development of all Products or Processes and the obtaining of Governmental Approvals necessary for commercialization of Products or Processes. Each Progress Report must include all of the following [***].

3.5 Licensee shall provide all reports with respect to its obligations under this Section 3 as set forth in Section 5.

4. PAYMENTS AND ROYALTIES

4.1 Milestone Payments.

(a) Licensee shall make milestone payments to Douglas within [***] of the achievement of the milestone events set forth in the table below by Licensee, its Affiliates, or its Sublicensees; *provided, however*, that if the Underlying Agreement is terminated and Licensee and Manchester thereafter enter into an agreement under which Manchester grants Licensee a license to practice the Underlying Patent Rights in the License Field, and if Licensee is obligated under such agreement to pay Manchester a milestone payment for occurrence of the same milestone event for which Licensee must pay Douglas as set forth in Table 1 below, then pursuant to Section 4.1(b) below, Licensee may deduct the amount it pays Manchester in respect of such milestone event against the corresponding payment payable by Licensee to Douglas as set forth in Table 1 below. Milestone payments are due only once and only as indicated herein. For the avoidance of doubt, each of the milestone payments shall be paid only once, regardless of the number of disease indications for a Product or Process developed under this Agreement.

Table 1. Clinical, Regulatory and Commercial Milestones – each payable only once on the first occurrence unless otherwise stated:

Milestone Event No.	**Milestone Event Description**	**Milestone Payment**
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]
5	[***]	[***]
6	[***]	[***]

Milestone Event No.	Milestone Event Description	Milestone Payment
7	[***]	[***]
8	[***]	[***]
9	[***]	[***]
10	[***]	[***]
11	[***]	[***]
12	[***]	[***]

[***]

(b) In the event that Licensee is obligated to pay Manchester a milestone payment for occurrence of the same milestone event for which Licensee must pay Douglas as set forth in Table 1 above, then as described in Section 4.1(a), Licensee may deduct the amount it pays Manchester in respect of such milestone event against the corresponding payment payable by Licensee to Douglas as set forth in Table 1 above; provided, however, that the total amount payable to Douglas for each milestone event set forth in Table 1 may not be reduced by more than [***].

(c) [***]

4.2 Royalties Income.

(a) Licensee shall pay Douglas during the Royalty Term, a royalty on annual Net Sales as specified in this Section 4.2.

(i) Valid Claim. During any period of time when the manufacture, use, sale, or import of the Products or Processes is Covered by a Valid Claim within the Patent Rights, Licensee shall pay Douglas a royalty on Annual Net Sales as outlined in Table 2.

(ii) No Valid Claim. During any period of time when the manufacture, use, sale, or import of the Products or Processes is not Covered by a Valid Claim, Licensee may reduce royalties payable hereunder in Table 2 by [***], provided that the minimum royalty rate payable to Douglas shall never fall below [***] (as set out in the Table 2 below):

Table 2. Royalty Rates based on Net Sales made during each calendar year ("Annual Net Sales") in the License Territory

Royalty Rate	Annual Net Sales
[***]	Net Sales < [***]
[***]	Portion of Annual Net Sales from [***] but less than [***]
[***]	Portion of Annual Net Sales from [***] but less than [***]
[***]	Portion of Annual Net Sales from [***] but less than [***]
[***]	Portion of Annual Net Sales from [***] but less than [***]
[***]	Portion of Annual Net Sales greater than [***]

For the sake of clarity, [***].

(b) In the event that Licensee is responsible for the payment of any royalties or license fees to third parties (including Manchester) in respect of the manufacture, use, sale, or import of Products or Processes, Licensee may reduce royalties payable hereunder by [***] of royalties and license fees owed by Licensee to such third parties in respect of the manufacture, use, sale, or import of Products

or Processes. For the foregoing reductions based on amounts paid by Licensee to third parties other than Manchester, in no event shall royalties payable to Douglas for Products or Processes under Section 4.2(a) be reduced by [***].

4.3 Sublicense Income.

(a) In the event that Licensee grants a Sublicense(s) to one or more Sublicensees, Licensee shall pay to Douglas, during the Royalty Term, a percentage of all Sublicense Income received from such Sublicensee(s) in accordance with Table 3.

(b) During any period of time when the manufacture, use, sale, or import of the Products or Processes is not Covered by a Valid Claim within the Patent Rights, Licensee may reduce the share of all Sublicense Income received by [***].

(c) [***]

(d) [***]

(e) [***]

Table 3. Revenue Share Payable to Douglas [***].

Revenue share to Douglas	**[***]**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For avoidance of doubt, [***].

(f) All payments due to Douglas under this Section 4.3 shall be due and payable by Licensee [***], and shall be accompanied by a report as set forth in Sections 5.3 and 5.4.

(g) Upon the expiration of a Royalty Term for a Product or Process in the License Territory, the licenses granted to Licensee under Section 2 with respect to such Product and Process in the License Territory shall be converted into fully paid-up, royalty-free, perpetual and irrevocable licenses.

4.4 Form of Payment.

(a) At Licensee's sole discretion but subject to applicable Trading Market limitations on the issuance of securities without stockholder approval (if any), Licensee may pay all or a portion of any given Milestone Payment(s) for milestones 1-6 indicated in Table 1 in Section 4.1 by issuing a number of shares of common stock of Registrant equal to the Stock Consideration. [***]

(b) Licensee's right to pay the Milestone Payment(s) using Stock Consideration shall be subject the following requirements:

(i) The Stock Consideration shall be registered for resale pursuant to an effective registration statement (the "Registration Statement") under the U.S. Securities Act of 1933, as amended (the "Securities Act") [***]. The common stock shall be listed for trading on the Nasdaq Capital Market or another Trading Market. Such common stock will be duly authorized and, when issued in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all liens, charges, pledges, security interests,

encumbrances, rights of first refusal, preemptive rights or other restrictions (other than restrictions under the Securities Act or other securities laws). [***].

(ii) [***]

(iii) [***]

(c) If Registrant is not in compliance with all applicable listing and corporate governance rules for Nasdaq or, if applicable, another Trading Market or any requirement set forth in Section 4.4(b) is not satisfied, Licensee shall be required to pay the Milestone Payment(s) in cash on the Milestone Payment date.

4.5 Withholding. If any applicable Law requires Licensee to withhold taxes with respect to any payment to be made by Licensee to Douglas pursuant to this Agreement, Licensee will notify Douglas of such withholding requirement prior to making the payment to Douglas [***]. Licensee will, in accordance with such law, withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish Douglas with proof of payment of such taxes [***]. [***].

4.6 Overdue Payments. The payments due under this Agreement shall, if overdue, bear interest [***], not to exceed the maximum permitted by law. Any such overdue payments when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not preclude Douglas from exercising any other rights it may have as a consequence of the lateness of any payment.

5. REPORTS AND RECORDS

5.1 Diligence Reports. [***], Licensee shall report in writing to Douglas on progress made toward achieving the objectives set forth in the Development Plan.

5.2 Milestone Achievement Notification. Licensee shall report to Douglas the dates on which it achieves the milestone events set forth in Section 4.1 [***].

5.3 Sales Reports. Licensee shall report to Douglas the date of the First Commercial Sale in the License Territory [***]. Following the First Commercial Sale in the License Territory, Licensee shall deliver a sales report to Douglas [***] the end of each Reporting Period with respect to Sales made during such Reporting Period. Each report under this Section 5.3 shall [***].

If no amounts are due to Licensee for any Reporting Period, the report shall so state.

5.4 Sublicense Income Reports. Licensee shall, along with delivering payment as set forth in Section 4.3, report to Douglas [***] the end of each Reporting Period with respect to Sublicense Income received during such Reporting Period, the amount of all Sublicense Income received by Licensee, and Licensee's calculation of the amount due and paid to Douglas from such income, [***].

5.5 Audit Rights. Licensee shall maintain, and shall cause each of its Affiliates and Sublicensees to maintain, complete and accurate records relating to Sales of Products and Processes and Sublicense Income, and the rights and obligations under Section 4 of this Agreement relative to any amounts payable to Douglas in relation to this Agreement, which records shall contain sufficient information to confirm the accuracy of any payments and reports delivered to Douglas hereunder. [***]

6. PATENT PROSECUTION AND MAINTENANCE

6.1 Ownership.

(a) Ownership of Inventions. Licensee shall solely and exclusively own all rights, title and interests in and to any Licensee Inventions, and except as expressly licensed by Licensee to Douglas under

Section 6.1(b) and subject to the restrictions therein, in and to any Improvements created, developed, conceived or reduced to practice solely by Licensee. Except as expressly licensed by Douglas to Licensee hereunder, and subject to any restrictions herein, Douglas shall solely and exclusively own all rights, title and interests in and to any Douglas Inventions and in and to any Improvements created, developed, conceived or reduced to practice solely by Douglas.

(b) Licensee Improvements. Licensee hereby grants and agrees to grant to Douglas a nonexclusive, royalty-free license to practice Improvements solely owned by Licensee outside the License Field and outside the License Territory during the term of this Agreement.

(c) Ownership of Non-Product Inventions: Each Party shall own a fifty percent (50%) undivided interest in all Non-Product Inventions. Except as expressly licensed by Douglas to Licensee hereunder and subject to any restrictions herein, each joint owner may make, sell, use, license, assign, pledge or keep Non-Product Inventions, and otherwise undertake all activities a sole owner might undertake with respect to such Non-Product Inventions, without the consent of and without accounting to the other joint owner, provided that any assignment, license or other disposition or use (a) shall at all times be and remain subject to the grants of rights and accompanying conditions and obligations with respect thereto under this Agreement, and (b) allow the Parties to exercise their rights and perform their obligations under this Agreement, in particular to develop and commercialize Products or Processes in at least the same scope as prior to such assignment, license or other such disposition.

(d) Inventorship. Inventorship for inventions (including inventions comprising Improvements) shall be determined in accordance with the patent laws of the United States (Title 35, United States Code). The Parties shall each maintain detailed laboratory notebooks, in accordance with customary practices in the industry, sufficient to evidence inventorship for purposes of patent filings.

6.2 Prosecution.

(a) Underlying Patent Rights. [***] certain prosecution and maintenance of patent applications and patents included in the Manchester Licensed IP that are subject to the Underlying Agreement (the "Underlying Patent Rights"). [***].

(b) Patent Rights held by Douglas. Douglas shall be responsible for the preparation, filing, prosecution and maintenance of all patent applications and patents included in Patent Rights that are not Underlying Patent Rights ("Douglas Patent Rights") within the License Territory (such activities constitute "Prosecution" or "Prosecute")). [***], Licensee shall reimburse Douglas for its direct, out of pocket costs and expenses incurred in Prosecution after the Effective Date; *provided, however*, that such costs and expense shall be prorated equally amongst other Douglas licensee(s) in the License Territory of the Douglas Patent Rights. [***]

(c) Any disputes in good faith by Licensee of invoices for patent expenses shall be resolved promptly and in good faith by the Parties.

6.3 Copies of Documents. [***]

7. THIRD PARTY INFRINGEMENT AND LEGAL ACTIONS

7.1 Notification Obligations. Each Party and Manchester agrees to immediately notify the other parties in writing upon becoming aware of any infringement of the Patent Rights in the License Field and provide to the other parties all reasonably available evidence of such infringement.

7.2 Infringement of Underlying Patent Rights.

(a) Manchester shall have the first right, but not the obligation, to protect and enforce the Underlying Patent Rights from or against infringement and prosecute infringers in the License Field in the License Territory, at its own expense. [***]

(b) [***], if Manchester decides not to pursue any legal action or remedy to abate the infringement of the Underlying Patent Rights, then (i) Manchester shall provide written notice to Licensee and Douglas that it waives its first right to prosecute infringement of the Underlying Patent Rights under Section 7.2(a), and (ii) the Parties agree that Licensee shall have the right, but not the obligation, to protect and enforce the Underlying Patent Rights from or against infringement and prosecute infringers in the License Field in the License Territory, at its own expense. [***]

(i) [***]

(c) If Licensee decides not to pursue any legal action or remedy to abate the infringement of the Underlying Patent Rights pursuant to Section 7.2(b), then (i) Licensee shall provide written notice to Manchester and Douglas that it waives its right to prosecute infringement of the Underlying Patent Rights under Section 7.2(b), and (ii) the Parties agree that Douglas shall have the right, but not the obligation, to protect and enforce the Underlying Patent Rights from or against infringement and prosecute infringers in the License Field in the License Territory, at its own expense. [***]

7.3 Infringement of Other Patent Rights.

(a) Licensee shall have the first right, but not the obligation, to protect and enforce the Patent Rights which are not Underlying Patent Rights from or against infringement and prosecute infringers in the License Field in the License Territory, at its own expense. [***]

(i) [***]

(b) [***], if Licensee decides not to pursue any legal action or remedy to abate the infringement of the Patent Rights that are not Underlying Patent Rights, then (i) Licensee shall provide written notice to Douglas that it waives its first right to prosecute infringement of the Patent Rights that are not Underlying Patent Rights under Section 7.3(a), and (ii) Douglas shall have the right, but not the obligation, to protect and enforce the Patent Rights that are not Underlying Patent Rights from or against such infringement and prosecute such infringers in the License Field in the License Territory, at its own expense. [***]

7.4 Douglas and Manchester Joined as Party-Plaintiff - Underlying Patent Rights. If Licensee elects to commence an action as described in Section 7.2(b) in respect to the Underlying Patent Rights, Douglas and Manchester shall each have, in their sole discretion, the option to join such action as party-plaintiffs. If Douglas and Manchester are required by law to join such action as party-plaintiffs, Douglas or Manchester may either (i) in their joint discretion, permit themselves to be joined as party-plaintiffs at the sole expense of Licensee, or (ii) assign to Licensee all of Douglas' or Manchester's s right, title and interest in and to the Patent Right which is the subject of such action (subject to any government rights under law and any other rights that others may have in such Patent Right). If Douglas and Manchester make such an assignment, such action by Licensee shall thereafter be brought or continued without Douglas or Manchester as a party; provided, however, that Douglas and Manchester shall continue to have all rights of prosecution and maintenance with respect to the Patent Rights and Licensee shall continue to meet all of its obligations under this Agreement as if the assigned Patent Right were still licensed to Licensee hereunder. For the sake of clarity, Manchester's rights specified in this Section only relate to the Underlying Patent Rights.

7.5 Douglas Joined as Party-Plaintiff - Patent Rights held by Douglas. If Licensee elects to commence an action as described in Section 7.3(a), Douglas shall have, in its sole discretion, the option to join such action as party-plaintiff. If Douglas is required by law to join such action as party-plaintiff, Douglas may either (i) in its joint discretion, permit itself to be joined as party-plaintiff at the sole expense of Licensee, or (ii) assign to Licensee all of Douglas' right, title and interest in and to the Patent Right which is the subject of such action (subject to any government rights under law

and any other rights that others may have in such Patent Right). If Douglas makes such an assignment, such action by Licensee shall thereafter be brought or continued without Douglas as a party; provided, however, that Douglas shall continue to have all rights of prosecution and maintenance with respect to the Patent Rights and Licensee shall continue to meet all of its obligations under this Agreement as if the assigned Patent Right were still licensed to Licensee hereunder.

7.6 Recovery. Any award paid by third parties as the result of proceedings brought by Licensee under Sections 7.2(b) or 7.3(a) (whether by way of settlement or otherwise) shall [***]:

(a) For any portion of the recovery or settlement, other than [***].

(b) For any portion of the recovery or settlement paid as enhanced damages for willful infringement: [***].

(c) For any portion of the recovery or settlement received in connection with any suit that is initiated by Douglas and in which Licensee was not a party in the litigation, [***].

7.7 Each Party will reasonably cooperate and assist with the other in litigation proceedings instituted hereunder but at the expense of the Party who initiated the suit (unless such suit is being jointly prosecuted by the Parties). For clarity, such requirement does not require a Party to join a suit unless otherwise specifically required under this Agreement. [***]

8. INDEMNIFICATION AND INSURANCE

8.1 Indemnification.

(a) Licensee shall indemnify, defend and hold harmless Douglas, its Affiliates, Manchester, its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the "Douglas Indemnitees") from and against any third party claims, actions, demands and proceedings (each a "Claim") brought or alleged against any of the Douglas Indemnitees, and shall pay all damages, losses and expenses (including reasonable attorney's fees and expenses of litigation) (collectively, "Losses") payable to such third party pursuant to such Claims, to the extent such Claim is arising out of or related to the exercise of any rights granted to Licensee under this Agreement (including Licensee's breach of Section 11.1), including without limitation any theory of product liability (including, but not limited to, actions in the form of contract, tort, warranty, or strict liability) concerning any product, process or service made, used, or sold or performed pursuant to any right or license granted under this Agreement, except to the extent such Losses arise from the breach of this Agreement or gross negligence or willful misconduct of a Douglas Indemnitee.

(b) Douglas shall indemnify, defend and hold harmless Licensee and its Affiliates and their directors, officers, employees, agents and their respective successors, heirs and assigns (the "Licensee Indemnitees") from and against any third party Claims brought or alleged against any of the Licensee Indemnitees, and shall pay all Losses payable to such third party pursuant to such Claims, to the extent such Claim is arising out of or related to Douglas' breach of Section 9.1, Section 9.2 or Section 9.3 or Douglas' gross negligence or willful misconduct.

(c) A Party that intends to claim indemnification under this Section 8.1 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor) of any Claim in respect of which the Indemnitee intends to claim such indemnification reasonably promptly after the Indemnitee is aware thereof (and in any event reasonably before any formal deadline for responding to such a Claim has passed), and shall permit the Indemnitor to assume the control of the defense and settlement of such Claim. The Indemnitor shall assume the defense of such Claim with counsel reasonably satisfactory to the Indemnitee; provided, however, that an Indemnitee shall have the right to retain its own counsel and participate in the defense thereof at its own cost and expense, and further provided, that the

Indemnitee shall have the right to retain its own counsel, at the expense of the Indemnitor, if representation of such Indemnitee by counsel retained by Indemnitor would be inappropriate because of a direct adverse conflict of interests of such Indemnitee and any other party represented by such counsel in such action or a related action.

(d) No Indemnitee may consent to any settlement or judgment of a Claim without the consent of the Indemnitor. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any matter covered by this indemnification. The Indemnitor agrees to keep the Indemnitee reasonably informed of the progress in the defense and disposition of such Claim.

(e) In the event a third party threatens in writing to bring a Claim against Licensee alleging the Product or Process infringes a third party's intellectual property rights, [***].

(f) This Section 8.1 shall survive expiration or termination of this Agreement.

8.2 Insurance.

(a) Licensee shall, at its sole cost and expense, procure and maintain insurance coverages for the Licensee and its employees through an insurer licensed to practice in the State of California, and Douglas shall qualify as an "additional insured" under such policies as follows: [***].

If Licensee desires to self-insure all or part of the limits described above [***]. The minimum amounts of insurance coverage required under this Section 8.2 shall not be construed to create a limit of Licensee's liability with respect to its indemnification under Section 8.1 of this Agreement.

(b) [***]

(c) [***]

(d) This Section 8.2 shall survive expiration or termination of this Agreement.

9. WARRANTIES; DISCLAIMER OF WARRANTIES; LIMITATION OF LIABILITY

9.1 Douglas Warranties. To the best actual knowledge of Douglas on the Effective Date, Douglas represents and warrants that Douglas is the exclusive licensee of the Underlying Patent Rights. Douglas represents and warrants that, as of the Effective Date, (i) it owns all right, title and interest in and to the patents and patent applications in the Patent Rights that are not Underlying Patent Rights, and that it has not granted any rights to any third party to such Patent Rights; (ii) Douglas has not received any written notice of any claims, liens or encumbrances with respect to the Patent Rights, (iii) Douglas has received no written claims of a third party to rights in the Patent Rights, (iv) to its best actual knowledge the Patent Rights are subsisting; (v) Douglas has not received any written claim or notice that the Patent Rights are invalid or unenforceable, and (vi) Douglas has not received any notice of any current claims, liens or encumbrances with respect to the rights and licenses to the Patent Rights granted to Licensee hereunder. Additionally, Douglas represents and warrants to Licensee that (a) Douglas has made available to Licensee all Technological Information in Douglas' possession and control pursuant to Section 2.5, (b) Douglas has not intentionally withheld any information in its control that is material to the Patent Rights and Technological Information, and (c) to Douglas' best actual knowledge, all information disclosed to Licensee prior to the Effective Date by Douglas relating to the Patent Rights and Technological Information is true, complete and accurate as of the date of disclosure.

9.2 Mutual Warranties. Each Party represents and warrants to the other Party that:

(a) this Agreement has been duly executed and delivered by and on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application

affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity;

(b) such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement; and

(c) such Party's execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable Law or any provision of the articles of incorporation, bylaws, limited partnership agreement, or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any applicable Law or any contractual obligation or court or administrative order by which such Party is bound.

9.3 Additional Warranties. Douglas represents, warrants and covenants to Licensee as follows:

(a) Douglas will, and will cause its Affiliates to, remain in compliance with the Underlying Agreement and will not without Licensee's prior written consent, terminate or amend the Underlying Agreement in a manner that adversely affects the rights granted to Licensee hereunder, or Douglas' ability to perform its obligations hereunder.

(b) Douglas will promptly send Licensee copies of all material correspondence to or from Manchester related to the Underlying Agreement. For the purposes of clarity, Douglas (and not Licensee) shall be responsible for all of the financial and other obligations of Douglas under the Underlying Agreement, including any and all financial obligations thereunder.

(c) Douglas will provide prompt notice to Licensee of any breach or default alleged in writing or request for amendment of the Underlying Agreement that may adversely affect the rights granted to Licensee hereunder, or Douglas' ability to perform its obligations hereunder. Upon prior written notice to Douglas, Licensee may remedy any such alleged breach or default of Douglas under the Underlying Agreement, including by making one or more payments to Manchester, and if Licensee makes any such payments, then it may credit the full amount of such payments against any amounts payable to Douglas hereunder.

(d) With respect to the Underlying Agreement, as of the Effective Date, (a) it is in full force and effect; (b) neither Douglas nor any of its Affiliates is in breach thereof; (c) neither Douglas nor any of its Affiliates has received any notice of breach or notice of threatened breach thereof; and (d) neither Douglas nor any of its Affiliates has received any notice from Manchester of intent to reduce the scope thereof.

(e) Douglas has provided to Licensee as of the Effective Date a true, correct and complete (with certain financial information redacted) copy of the Underlying Agreement, including any and all amendments, restatements, side letters, and other modifications thereto.

(f) The payments required to be paid by Licensee pursuant to this Agreement are sufficient to satisfy Douglas' financial obligations under the Underlying Agreement.

(g) Douglas will not enter into any agreement with any third party that is in conflict with the rights granted to Licensee under this Agreement and will not take any action that would prevent it from granting the rights granted to Licensee under this Agreement or that would otherwise materially conflict with or adversely affect the rights granted to Licensee under this Agreement.

(h) Douglas has full power and authority to grant licenses under the Licensed IP to Licensee as contemplated under this Agreement.

9.4 No Warranties. EXCEPT WITH RESPECT TO THE EXPRESS WARRANTIES MADE IN SECTION 9.1, SECTION 9.2 AND SECTION 9.3, DOUGLAS AND ITS LICENSORS MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE PATENT RIGHTS AND THE RIGHTS GRANTED HEREUNDER, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, VALIDITY OF PATENT RIGHTS CLAIMS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, AND HEREBY DISCLAIMS THE SAME. SPECIFICALLY, AND NOT TO LIMIT THE FOREGOING, DOUGLAS AND ITS LICENSORS MAKE NO WARRANTY OR REPRESENTATION (i) REGARDING THE VALIDITY OR SCOPE OF ANY OF THE CLAIM(S), WHETHER ISSUED OR PENDING, OF ANY OF THE PATENT RIGHTS, AND (ii) THAT THE EXPLOITATION OF THE PATENT RIGHTS OR ANY PRODUCT OR PROCESS WILL NOT INFRINGE ANY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

9.5 Limitation of Liability. IN NO EVENT SHALL DOUGLAS OR LICENSEE OR ANY OF THEIR AFFILIATES OR ANY OF THEIR LICENSORS, DIRECTORS, OFFICERS, MEDICAL OR EMPLOYEES, CONSULTANTS AND AGENTS BE LIABLE HEREUNDER FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE LICENSE OR RIGHTS GRANTED HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING; PROVIDED HOWEVER THAT NOTHING IN THIS SECTION 9.5 SHALL BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 8 WITH RESPECT TO THIRD PARTY CLAIMS.

9.6 Underlying Agreement. Licensee has had an opportunity to review the Patent Rights and the Underlying Agreement and acknowledges that field of use in the Underlying Agreement is limited to the use of certain anti-retrovirals hitherto used orally to treat HIV-1 infections to be used topically to treat and/or prevent pre-invasive CIN 1/2/3 cervical cancer in humans.

10. TERM AND TERMINATION

10.1 Term. The term of the Agreement will commence upon the Effective Date and continue until the expiration of the last-to-expire Royalty Term, unless this Agreement is terminated earlier in accordance with any of the other provisions of Section 10. Upon expiration per this Section 10.1, the licenses granted herein shall convert automatically to fully paid irrevocable, perpetual licenses. For clarity, the grant conversion of this Section 10.1 shall not apply if the Agreement is terminated pursuant to Sections 10.2, 10.3 or 10.4.

10.2 Termination for Failure to Pay. If Licensee fails to make any payment due hereunder, Douglas shall have the right to terminate this Agreement upon [***] notice, unless, subject to Licensee's right to dispute such payment under the provisions of Section 12.13, Licensee makes such payments plus any interest due, as set forth in Section 4.6, within [***]. If undisputed payments are not made, Douglas may immediately terminate this Agreement at the end of [***]. Licensee shall be entitled to [***] such cure periods [***].

10.3 Termination for Insurance and Insolvency.

(a) Insurance. Douglas shall have the right to terminate this Agreement if Licensee fails to maintain the insurance required by Section 8.2 and does not cure such failure within [***].

(b) Insolvency and other Bankruptcy Related Events. Douglas shall have the right to terminate this Agreement immediately upon written notice to Licensee with no further notice obligation or opportunity to cure if Licensee: (i) shall become insolvent; (ii) shall make an assignment for the benefit of creditors; or (iii) or shall have a petition in bankruptcy filed against it, which petition is not dismissed within [***].

10.4 Termination for Non-Financial Default. If Licensee or any of its Affiliates materially breaches any of its obligations under this Agreement not otherwise covered by the provisions of Section 10.2 and 10.3, and if such material breach has not been cured within [***], then Douglas may immediately terminate this Agreement and/or any license granted hereunder at the end of [***]. If Douglas notifies Licensee of a material breach as described herein, the Parties shall promptly meet in an effort to resolve any good faith dispute with respect to such breach in accordance with Section 12.13.

10.5 Challenging Validity. During the term of this Agreement, Licensee shall not Challenge, and shall contractually restrict its Affiliates and Sublicensees from Challenging, the Patent Rights and in the event of any breach of this provision, Douglas shall have the right to terminate this Agreement and any license (and Sublicense in the case of a Challenge from a Sublicensee) granted hereunder immediately; *provided, however*, that Douglas shall not terminate this Agreement for a Challenge by a Sublicensee if such Challenge is dismissed [***]. In addition, if the Patent Rights are upheld as a result of the Challenge, Licensee shall reimburse Douglas for its reasonable legal costs and expenses incurred in defending any such Challenge. Licensee or its Affiliate or a Sublicensee will be deemed to have made a "Challenge" of the Patent Rights if such entity: [***]. Notwithstanding the foregoing, any response by Licensee, its Affiliates or Sublicensee in response to any suit, proceeding, or other action brought directly or indirectly by Douglas or any of its Affiliates or Manchester against Licensee, its Affiliates or Sublicensee shall not be deemed a Challenge.

10.6 Termination by Licensee. Licensee shall have the right to terminate this Agreement by giving [***] notice to Douglas (but if such termination occurs prior to receipt of Governmental Approval, then such notice [***], and upon such termination shall immediately cease all use and Sales of Products and Processes in the License Territory, subject to Section 10.9.

10.7 Effect of Termination.

(a) In the event the Agreement is terminated by Licensee in accordance with Section 10.6, and in the event of termination of this Agreement by Douglas in the event of material uncured breach by Licensee pursuant to Section 10.4, Douglas will have full access, including the right to use and reference, to all Product data generated during the term of this Agreement that is owned by Licensee and to which Licensee has the right to make available to Douglas. If this Agreement is terminated by Licensee in accordance with Section 10.6, such access shall be conditional upon and pursuant to a commercially reasonable royalty as the Parties may agree in writing. In the event of termination of this Agreement by Douglas in the event of material uncured breach by Licensee pursuant to Section 10.4, such access shall be royalty-free. Upon the termination of this Agreement, any and all Sublicenses to a Sublicensee that has operations directed to the research and development of pharmaceutical drug products or is a distributor of such products shall remain in effect and be assigned to Douglas on substantially the same terms as set forth in such Sublicense, and Douglas shall be deemed for all purposes to be the licensor thereunder, provided that (i) such Sublicensee is in good standing under its Sublicense agreement at the time of such termination; (ii) the Sublicense is consistent with the terms of this Agreement; (iii) Douglas shall have no obligations under such Sublicenses other than to preserve the effectiveness, scope, and validity of the licenses granted therein under the Licensed IP; (iv) the relevant Sublicense(s), when taken together, provide Douglas with similar benefits as this Agreement, (v) Douglas shall not assume any obligation of Licensee to such Sublicensee pursuant to any representation, warranty or indemnification provision; and (vi) further provided that such Sublicensee enters into an agreement directly with Douglas to effectuate such assignment. Douglas shall be entitled to all payments due to Licensee (but excluding any duplicate payments) from each Sublicensee under any such Sublicense in accordance with the terms of such Sublicense; and such Sublicense shall be deemed assigned to Douglas if necessary to ensure continued payments.

(b) In the event the Underlying Agreement is terminated for any reason, Licensee may, in its discretion, assume the obligations and rights of Douglas under the Underlying Agreement pursuant to the terms of Licensee's direct written agreement with Manchester (the "Manchester Side Letter") in accordance with the terms of the Manchester Side Letter such that Licensee's rights to the Patent

Rights and Technological Information will remain uninterrupted regardless of any breach or default of Douglas with regards to the Underlying Agreement.

10.8 Effects of Termination of Agreement. Upon termination of this Agreement or any of the licenses hereunder for any reason, final reports in accordance with Section 5 shall be submitted to Douglas and all royalties and other payments, accrued or due to Douglas as of the termination date shall become immediately payable. Licensee shall cease, and shall cause its Affiliates and Sublicensees to cease under any Sublicense granted by Licensee, all Sales and uses of Products and Processes upon such termination and all use of the Manchester Licensed IP, subject to Section 10.7 and Section 10.9. The termination or expiration of this Agreement or any license granted hereunder shall not relieve Licensee, its Affiliates or Sublicensees of obligations arising before such termination or expiration.

10.9 Inventory. Upon early termination of this Agreement other than pursuant to Section 10.4, Licensee and its Affiliates and Sublicensees, subject to Section 10.7, may complete and sell any work-in-progress and inventory of Products that exist as of the effective date of termination provided [***]. Upon expiration of this Agreement, Licensee shall pay to Douglas the royalties or Sublicense Income share as set forth in Section 4.2 and Section 4.3 for Sales of any Product that was in inventory or was a work-in progress on the date of expiration of the Agreement.

10.10 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder, and as a licensee of such rights under this Agreement, Licensee shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

11. COVENANTS

11.1 Compliance. Licensee shall have the sole obligation for compliance with, and shall ensure that any Affiliates and Sublicensees comply with, all government statutes and regulations that govern Products and Processes, including, but not limited to, those of the FDA and the Export Administration, as amended. Licensee agrees that it shall be solely responsible for obtaining any necessary licenses to export, re-export, or import Products or Processes covered by Patent Rights and/or Confidential Information.

11.2 Patent Numbers. To the extent required by applicable Law, Licensee shall use commercially reasonable efforts to properly mark all Products or their packaging in accordance with the applicable patent marking laws.

11.3 Use of Names. Licensee, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Douglas, Manchester or any Douglas or Manchester employee or representative, without the prior written consent of Douglas or Manchester (as appropriate), such consent not to be unreasonably withheld or delayed. Notwithstanding the foregoing, Licensee may use the name of Douglas in a non-misleading and factual manner solely in (a) [***], and (b) any securities reports required to be filed with the Securities and Exchange Commission, or as otherwise required pursuant to applicable Law.

11.4 Publicity. Subject to Section 11.3 hereunder, no Party shall issue any press release or public announcement relating to this Agreement or the subject matter of this Agreement without the prior written approval of the other Party, and without the provision of a reasonable opportunity for the other Party to review and comment on any such press release or announcement. Douglas will not unreasonably withhold, condition or delay its approval of Licensee's press release announcing the execution of this Agreement. [***]

11.5 Ancillary Agreements.

Following the Effective Date, Licensee and Douglas shall undertake good faith, diligent efforts to promptly enter into commercially reasonable agreements for the following:

(a) Douglas to support Licensee's product development efforts set forth in the Development Plans reasonably acceptable to Douglas pursuant to Section 3.3 in accordance with the terms of a development services agreement;

(b) Licensee to purchase from Douglas clinical trial supplies of the Product in accordance with the terms of a clinical trial product supply agreement; and

(c) Licensee to purchase from Douglas a commercial supply of the Products manufactured by Douglas in New Zealand in accordance with the terms of a commercial supply agreement.

(d) Licensee will use commercially reasonable efforts to cause any third parties with whom Licensee enters into manufacturing agreements to include Douglas and Manchester as an indemnitee under such agreement.

12. MISCELLANEOUS

12.1 Confidentiality. Each Party shall treat all information received from the other Party in connection with this Agreement in accordance with the provisions of Exhibit C. Without limiting the foregoing, Licensee agrees to treat all information related to prosecution and maintenance of Patent Rights as Confidential Information in accordance with the provisions of Exhibit C, and Douglas agrees to treat all information received in reports delivered under Section 5 as Licensee's Confidential Information in accordance with the provisions of Exhibit C.

12.2 Entire Agreement. This Agreement constitutes the entire understanding between the Parties with respect to the subject matter hereof and supersedes that certain Non-Binding Term Sheet signed by the Parties [***].

12.3 Notices. Any notices, waivers, or other legal or formal communications required under or pertaining to this Agreement shall be in writing and shall be delivered by international commercial courier service (e.g., Federal Express). Notices will be deemed effective upon receipt. Unless changed in writing in accordance with this Section, the notice address for Licensee shall be as follows:

If to Licensee:	Daré Bioscience, Inc. 3655 Nobel Drive, Suite 260 San Diego, California 92122 United States of America Attention: Chief Executive Officer
If to Douglas:	Douglas Pharmaceuticals, Ltd. [***]
If to Manchester	The University of Manchester [***]

12.4 Amendment; Waiver. This Agreement may be amended and any of its terms or conditions may be waived only by a written instrument executed by an authorized signatory of the Parties or, in the case of a waiver, by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no matter affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term shall be deemed as a further or continuing waiver of such condition or term or of any other condition or term.

12.5 Binding Effect. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.

12.6 Assignment. This Agreement may not be assigned by either Party without the other Party's written consent, provided that no such consent of the other Party will be required for assignment of the Agreement (a) in connection with the transfer or sale of all or substantially all of the assets or business of such Party to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise, or similar change of control, or (b) to any Affiliate.

12.7 Force Majeure. Neither Party shall be responsible for delays resulting from causes beyond the reasonable control of such Party (which shall not relate to delays in payment), including without limitation fire, explosion, flood, war, sabotage, terrorism, strike or riot, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

12.8 Governing Law. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the Delaware, excluding with respect to conflict of laws, except that questions affecting the construction and effect of any patent shall be determined by the U.S. Law.

12.9 Severability. If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable Law from time to time in effect during the term hereof, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby. It is further the intention of the Parties that in lieu of each such provision which is invalid, illegal or unenforceable, there be substituted or added as part of this Agreement a provision which shall be as similar as possible in economic and business objectives as intended by the Parties to such invalid, illegal or enforceable provision, but shall be valid, legal and enforceable.

12.10 Survival. In addition to any specific survival references in this Agreement, Sections 2.3, 4.6, 5, 8, 9, 10.7, 10.8, 10.9, 10.10 and 12 shall survive termination or expiration of this Agreement. Any other rights, responsibilities, obligations, covenants and warranties which by their nature should survive this Agreement shall similarly survive and remain in effect.

12.11 Interpretation. The Parties hereto are sophisticated, have had the opportunity to consult legal counsel with respect to this transaction and hereby waive any presumptions of any statutory or common law rule relating to the interpretation of contracts against the drafter.

12.12 Headings. All headings are for convenience only and shall not affect the meaning of any provision of this Agreement.

12.13 Dispute Resolution.

(a) Any dispute or issue relating to or in connection with this Agreement (a "Dispute") shall initially be referred to [***] to resolve the Dispute. However, notwithstanding any of the terms of this Section 12.13 and without limiting any other remedies that may be available, each Party shall have the right to seek immediate injunctive relief and other equitable relief from any court of competent jurisdiction to enjoin any breach or violation of this Agreement concerning confidential information or any other intellectual property licensed under this Agreement, without any obligation to undertake extra-judicial dispute resolution of any such Dispute or claim or otherwise to comply with this Section 12.13. It is understood and agreed that during the pendency of a Dispute pursuant to this Section 12.13, the terms and conditions of this Agreement shall remain in effect, any termination right shall be suspended, and the Parties shall continue to perform all of their respective obligations hereunder.

(b) If [***] are unable to resolve the Dispute within [***], and a Party wishes to pursue the matter, any dispute, controversy or claim arising out of, relating to or in connection with this Agreement, including the breach, termination, or validity thereof, shall be resolved by final and binding arbitration administered by the International Centre for Dispute Resolution in accordance with its International Arbitration Rules. The arbitration will be conducted in the English language and will

occur in Wilmington, Delaware. Any arbitration will be in front of a single arbitrator. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT EITHER OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.

(c) Each Party shall bear its own costs in obtaining the dispute resolution, as outlined above.

12.14 Third Party Rights. The Parties agree that Manchester shall be a third-party beneficiary under this Agreement and shall have the right directly to enforce all its rights under this Agreement. Notwithstanding the foregoing, Douglas and Licensee shall be permitted, in their sole discretion, to make amendments and grant waivers to any of the provisions of this Agreement without the consent of Manchester except to the extent such amendment or waiver has a material adverse effect on Manchester that is disproportionate to the effect on Douglas.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives effective as of the Effective Date.

DOUGLAS PHARMACEUTICALS, LTD.

By: /s/ Jeff Douglas
Name: Jeff Douglas
Title: Managing Director

DARÉ BIOSCIENCE, INC.

By: /s/ Sabrina Martucci Johnson
Name: Sabrina Martucci Johnson
Title: CEO

Exhibit A

Licensed Patent Rights

[***]

Exhibit B

Technological Information

[***]

Exhibit C

CONFIDENTIALITY TERMS AND CONDITIONS

[***]

Exhibit D

CLINICAL DATA

[***]

Exhibit 10.11

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

GRANT AGREEMENT

Investment ID INV-026060

AGREEMENT SUMMARY & SIGNATURE PAGE

GRANTEE INFORMATION	
Name:	Dare Bioscience, Inc.
Tax Status:	Not exempt from federal income tax under U.S. IRC § 501(c)(3) You confirm that the above information is correct and agree to notify the Foundation immediately of any change.
Expenditure Responsibility:	This Agreement is subject to "expenditure responsibility" requirements under the U.S. Internal Revenue Code.
Mailing Address:	3655 Nobel Drive Suite 260, San Diego, California 92122, USA
Primary Contact:	Nicolas Pacelli, Vice President, Business Development, [***]

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, Washington 98102, USA
Primary Contact:	Kirsten Vogelsong, Senior Program Officer, Contraceptive Development, Integrated Development, [***]

AGREEMENT INFORMATION	
Title:	Personal Contraceptive System (DARE LARC1)
"Charitable Purpose":	To advance the development of a novel long-acting, user-controlled hormonal contraceptive implant suitable for use by women in low-resource settings
"Start Date":	Date of last signature
"End Date":	November 1, 2026
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Investment Document (date submitted [***]) • Results Framework and Tracker (date submitted [***]) • Budget (date submitted [***])

THIS AGREEMENT is between Dare Bioscience, Inc. ("Dare Bioscience", "You" or "Grantee") and the Bill & Melinda Gates Foundation ("Foundation"), and is effective as of date of last signature. Each party to this Agreement may be referred to individually as a "Party" and together as the "Parties." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

/s/ Kirsten Vogelsong
By: Kirsten Vogelsong
Title: Senior Program Officer

June 24, 2021
Date

DARE BIOSCIENCE, INC.

/s/ Sabrina Johnson
By: Sabrina Johnson
Title: CEO

June 30, 2021
Date

GRANT AGREEMENT
Investment ID INV-026060

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT
The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE
Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING
You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

ACCOUNTING FOR PERSONNEL TIME
You will track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Grant Funds. Such individuals will keep records (e.g., timesheets) of actual time worked on the Project in increments of sixty minutes or less and brief descriptions of tasks performed. You will report actual time worked consistent with those records in Your progress and final budget reports. You will submit copies of such records to the Foundation upon request.

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		[***]	$11,453,099
	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	[***]	Up to $[***]
[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
[***]	[***]	[***]		
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[***]	[***]	[***]	[***]	Up to $[***]
[***]	[***]	[***]		
	[***]	[***]	[***]	Up to $[***]
[***]	[***]	[***]	[***]	Up to $[***]

[***]	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
[***]	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
			Total Grant Amount	**Up to $48,945,928**

GRANT AGREEMENT
Investment ID INV-026060

ATTACHMENT B
TERMS & CONDITIONS

This Agreement is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE
The Foundation is awarding You this grant to carry out the project described in the Investment Document ("*Project*") in order to further the Charitable Purpose. The Foundation, in its discretion, may approve in writing any request by You to make non-material changes to the Investment Document.

MANAGEMENT OF FUNDS

USE OF FUNDS
You may not use funds provided under this Agreement *("Grant Funds")* for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date. At the Foundation's request, You will repay any portion of Grant Funds and/or Income used or committed in material breach of this Agreement, as determined by the Foundation in its discretion.

INVESTMENT OF FUNDS
You must invest Grant Funds in highly liquid investments with the primary objective of preservation of principal (e.g., interest-bearing bank accounts or a registered money market mutual fund) so that the Grant Funds are available for the Project. Together with any progress or final reports required under this Agreement, You must report the amount of any currency conversion gains (or losses) and the amount of any interest or other income generated by the Grant Funds (collectively, "*Income*"). Any Income must be used for the Project.

SEGREGATION OF FUNDS
You must maintain Grant Funds in a physically separate bank account or a separate bookkeeping account maintained as part of Your financial records and dedicated to the Project.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT
You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

HUMANITARIAN LICENSE
Subject to applicable laws and for the purpose of achieving Global Access, You grant the Foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and Essential Background Technology. “Essential Background Technology” means Background Technology that is: (a) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (b) either incorporated into a Funded Development or reasonably required to exercise the license to a Funded Development. You confirm that You have retained sufficient rights in the Funded Developments and Essential Background Technology to grant this license. You must ensure this license

survives the assignment or transfer of Funded Developments or Essential Background Technology. On request, You must promptly make available the Funded Developments and Essential Background Technology to the Foundation for use solely under this license. If You demonstrate to the satisfaction of the Foundation that Global Access can best be achieved without this license, the Foundation and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION
Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. "Publication" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, You agree to adhere to the Foundation's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

INTELLECTUAL PROPERTY REPORTING
During the term of this Agreement and for 5 years after, You will submit upon request annual intellectual property reports relating to the Funded Developments, Background Technology, and any related agreements using the Foundation's templates or forms, which the Foundation may modify from time to time.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS
You may not make subgrants under this Agreement. You have the exclusive right to select subcontractors to assist with the Project.

RESPONSIBILITY FOR OTHERS
You are responsible for (a) all acts and omissions of any of Your trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project, and (b) ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM
You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY
You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

POLITICAL ACTIVITY AND ADVOCACY
You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You may not use Grant Funds to support lobbying activity or to otherwise support

attempts to influence local, state, federal, or foreign legislation. Your strategies and activities, and any materials produced with Grant Funds, must comply with applicable local, state, federal, or foreign lobbying law. You agree to comply with lobbying, gift, and ethics rules applicable to the Project.

OTHER

PUBLICITY

A Party may publicly disclose information about the award of this grant, including the other Party's name, the total amount awarded, and a description of the Project, provided that a Party obtains prior written approval before using the other Party's name for promotional purposes or logo for any purpose. Any public disclosure by You or Your subgrantees, subcontractors, contingent workers, agents, or affiliates must be made in accordance with the Foundation's then-current brand guidelines, which are available at: www.gatesfoundation.org/brandguidelines.

LEGAL ENTITY AND AUTHORITY

You confirm that: (a) You are an entity duly organized or formed, qualified to do business, and in good standing under the laws of the jurisdiction in which You are organized or formed; (b) You are not an individual (i.e., a natural person) or a disregarded entity (e.g., a sole proprietor or sole-owner entity) under U.S. law; (c) You have the right to enter into and fully perform this Agreement; and (d) Your performance will not violate any agreement or obligation between You and any third party. You will notify the Foundation immediately if any of this changes during the term of this Agreement.

COMPLIANCE WITH LAWS

In carrying out the Project, You will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.

COMPLIANCE WITH REQUIREMENTS

You will conduct, control, manage, and monitor the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards ("*Requirements*"). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of Your annual progress report to the Foundation, You must report whether the Project activities were conducted in compliance with all Requirements.

If the Project involves:
a. any protected information (including personally identifiable, protected health, or third-party confidential), You will not disclose this information to the Foundation without obtaining the Foundation's prior written approval and all necessary consents to disclose such information;
b. children or vulnerable subjects, You will obtain any necessary consents and approvals unique to these subjects; and/or
c. any trial involving human subjects, You will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the Foundation in reviewing documents and providing input or funding does not modify Your responsibility for determining and complying with all Requirements for the Project.

RELIANCE

You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

INDEMNIFICATION

If the Project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("*Indemnified Activities*"), You will indemnify, defend, and hold harmless the Foundation and its trustees, employees, and agents ("*Indemnified Parties*") from and against any and all demands, claims,

actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "*Claims*") arising out of or relating to the acts or omissions, actual or alleged, of You or Your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the Foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of Your governmental and sovereign immunities, if any.

INSURANCE
You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted industry standards and as required by law. You will ensure Your subgrantees and subcontractors maintain insurance coverage consistent with this section.

TERM AND TERMINATION

TERM
This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement. The Foundation, in its discretion, may approve in writing any request by You for a no-cost extension, including amending the End Date and adjusting any affected reporting requirements.

TERMINATION
The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS
Any Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation.

MONITORING, REVIEW, AND AUDIT
The Foundation may monitor and review Your use of the Grant Funds, performance of the Project, and compliance with this Agreement, which may include onsite visits to assess Your organization's governance, management and operations, discuss Your program and finances, and review relevant financial and other records and materials. In addition, the Foundation may conduct audits, including onsite audits, at any time during the term of this Agreement, and within four years after Grant Funds have been fully spent. Any onsite visit or audit shall be conducted at the Foundation's expense, following prior written notice, during normal business hours, and no more than once during any 12-month period.

INTERNAL OR THIRD PARTY AUDIT
If during the term of this Agreement You are audited by your internal audit department or by a third party, You will provide the audit report to the Foundation upon request, including the management letter and a detailed plan for remedying any deficiencies observed ("*Remediation Plan*"). The Remediation Plan must include (a) details of actions You will take to correct any deficiencies observed, and (b) target dates for successful completion of the actions to correct the deficiencies.

RECORD KEEPING
You will maintain complete and accurate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Grant Funds have been fully spent. At the Foundation's request, You will make such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used or committed.

SURVIVAL
A Party's obligations under this Agreement will be continuous and survive expiration or termination of this Agreement as expressly provided in this Agreement or otherwise required by law or intended by their nature.

GENERAL

ENTIRE AGREEMENT, CONFLICTS, AND AMENDMENTS
This Agreement contains the entire agreement of the Parties and supersedes all prior and contemporaneous agreements concerning its subject matter. If there is a conflict between this Agreement and the Investment Document this Agreement will prevail. Except as specifically permitted in this Agreement, no modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

NOTICES AND APPROVALS
Written notices, requests, and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the Agreement Summary & Signature Page, or as otherwise directed by the other Party.

SEVERABILITY
Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

ASSIGNMENT
You may not assign, or transfer by operation of law or court order, any of Your rights or obligations under this Agreement without the Foundation's prior written approval. This Agreement will bind and benefit any permitted successors and assigns.

COUNTERPARTS AND ELECTRONIC SIGNATURES
Except as may be prohibited by applicable law or regulation, this Agreement and any amendment may be signed in counterparts, by facsimile, PDF, or other electronic means, each of which will be deemed an original and all of which when taken together will constitute one agreement. Facsimile and electronic signatures will be binding for all purposes.

AMENDMENT 1
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant Agreement between the Bill & Melinda Gates Foundation and Daré Bioscience, Inc., effective June 30, 2021, and bearing Investment ID INV-026060
Amendment Purpose:	Reporting & Payment Schedule Change
"Amendment Date":	November 23, 2022

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone*, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Grant Agreement	[***]	July 2021	$11,453,099.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]	July 2022	$7,960,608.00
[***]	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		

[***]	[***]	[***]	November 2022	$4,436,204.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
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	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		

[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
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[***]	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
Amended Total Grant Amount				**Up to $48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 2
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	September 14, 2023

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement	[***]	July 2021	$11,453,099.00
	[***]	[***]	July 2022	$7,960,608.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
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[***]	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	November 2022	$4,436,204.00
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	September 2023	$4,500,000.00
	[***]	[***]		
	[***]	[***]		
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[***]	[***]	[***]		
			Amended Total Grant Amount	**$48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 3
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	Date of this email

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		July 2021	$11,453,099.00
	[***]			
	[***]			
	[***]		July 2022	$7,960,608.00
	[***]			
	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]		November 2022	$4,436,204.00

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	[***]			
[***]	[***]			
Amended Total Grant Amount				**Up to $48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 4
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	Date of this email

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		July 2021	$11,453,099.00
	[***]			
	[***]			
	[***]		July 2022	$7,960,608.00
	[***]			
	[***]			
	[***]			
[***]	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]			
	[***]		November 2022	$4,436,204.00

	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]		September 2023	$4,500,000.00
	[***]			
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[***]	[***]			
	[***]			
	[***]		April 2024	$1,000,000.00
	[***]			
	[***]			
[***]	[***]		November 2024	$2,500,000.00
[***]	[***]	[***]	[***]	$[***]
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Amended Total Grant Amount				**Up to $48,945,928.00**

As provided in the Agreement, signatures are not required.

Exhibit 10.12

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

GRANT AGREEMENT

Investment ID INV-074353

AGREEMENT SUMMARY & SIGNATURE PAGE

GRANTEE INFORMATION	
Name:	Dare Bioscience, Inc.
Tax Status:	Not exempt from federal income tax under U.S. IRC § 501(c)(3) You confirm that the above information is correct and agree to notify the Foundation immediately of any change.
Expenditure Responsibility:	This Agreement is subject to "expenditure responsibility" requirements under the U.S. Internal Revenue Code.
Mailing Address:	3655 Nobel Drive Suite 260, San Diego, California 92122, USA
Primary Contact:	Elizabeth Proos, Vice President, Product Development, [***]

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, Washington 98102, USA
Primary Contact:	Kirsten Vogelsong, Senior Program Officer, Contraceptive Development, [***]

AGREEMENT INFORMATION	
Title:	Development of a novel non-hormonal contraceptive
"Charitable Purpose":	To de-risk the development of a non-hormonal intravaginal contraceptive, suitable for and acceptable to women in LMIC settings who need or would prefer to use such a product to avoid an unplanned pregnancy.
"Start Date":	Date of last signature
"End Date":	October 31, 2026
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Investment Document (date submitted [***]) • Budget (date submitted [***])

THIS AGREEMENT is between Dare Bioscience, Inc. *("You" or "Grantee")* and the Bill & Melinda Gates Foundation ("*Foundation*"), and is effective as of date of last signature. Each party to this Agreement may be referred to individually as a "*Party*" and together as the "*Parties*." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

/s/ Kirsten Vogelsong
By: Kirsten Vogelsong
Title: Senior Program Officer

November 11, 2024
Date

DARE BIOSCIENCE, INC.

/s/ Sabrina Johnson
By: Sabrina Johnson
Title: CEO

November 11, 2024
Date

GRANT AGREEMENT
Investment ID INV-074353

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT
The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE
Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING
You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

In addition to reports listed below that are required to be submitted to the Foundation, You will furnish to the Foundation, within 30 days after they become available, quarterly (unaudited) and annual (audited) financial statements. You will also inform the Foundation, within a reasonable time of discovery, of any situation where Your existing cash reserves are not sufficient for the purposes of continuing Your standard business operations for the next 240 days.

ACCOUNTING FOR PERSONNEL TIME
You will track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Grant Funds. Such individuals will keep records (e.g., timesheets) of actual time worked on the Project in increments of sixty minutes or less and brief descriptions of tasks performed. You will report actual time worked consistent with those records in Your progress and final budget reports. You will submit copies of such records to the Foundation upon request.

REPORTING & PAYMENT SCHEDULE

Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement	[***]	[***]	$5,393,118.00
	[***]	[***]		

[***]	[***]	[***]		
	[***]			
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	[***]	[***]		
[***]	[***]	[***]		
			Total Grant Amount	**Up to $10,683,142.00**

GRANT AGREEMENT
Investment ID INV-074353

ATTACHMENT B
TERMS & CONDITIONS

This Agreement is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE
The Foundation is awarding You this grant to carry out the project described in the Investment Document ("*Project*") in order to further the Charitable Purpose. The Foundation, in its discretion, may approve in writing any request by You to make non-material changes to the Investment Document.

MANAGEMENT OF FUNDS

USE OF FUNDS
You may not use funds provided under this Agreement *("Grant Funds")* for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date. At the Foundation's request, You will repay any portion of Grant Funds and/or Income used or committed in material breach of this Agreement, as determined by the Foundation in its discretion.

INVESTMENT OF FUNDS
You must invest Grant Funds in highly liquid investments with the primary objective of preservation of principal (e.g., interest-bearing bank accounts or a registered money market mutual fund) so that the Grant Funds are available for the Project. Together with any progress or final reports required under this Agreement, You must report the amount of any currency conversion gains (or losses) and the amount of any interest or other income generated by the Grant Funds (collectively, "*Income*"). Any Income must be used for the Project.

SEGREGATION OF FUNDS
You must maintain Grant Funds in a physically separate bank account or a separate bookkeeping account maintained as part of Your financial records and dedicated to the Project.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT
You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

GLOBAL ACCESS MILESTONES
[***]

HUMANITARIAN LICENSE
Subject to applicable laws and for the purpose of achieving Global Access, You grant the Foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and Essential Background Technology. “Essential Background Technology” means Background Technology that is: (a) owned, controlled, or developed by You, or in-licensed with the right to

sublicense; and (b) either incorporated into a Funded Development or reasonably required to exercise the license to a Funded Development. You confirm that You have retained sufficient rights in the Funded Developments and Essential Background Technology to grant this license. You must ensure this license survives the assignment or transfer of Funded Developments or Essential Background Technology. On request, You must promptly make available the Funded Developments and Essential Background Technology to the Foundation for use solely under this license. If You demonstrate to the satisfaction of the Foundation that Global Access can best be achieved without this license, the Foundation and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION
Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. "Publication" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, You agree to adhere to the Foundation's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

INTELLECTUAL PROPERTY REPORTING
During the term of this Agreement and for 5 years after, You will submit upon request annual intellectual property reports relating to the Funded Developments, Background Technology, and any related agreements using the Foundation's templates or forms, which the Foundation may modify from time to time.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS
You may not make subgrants under this Agreement. You have the exclusive right to select subcontractors to assist with the Project.

RESPONSIBILITY FOR OTHERS
You are responsible for (a) all acts and omissions of any of Your trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project, and (b) ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM
You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region and so-called Luhansk and Donetsk People's Republics of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY
You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

POLITICAL ACTIVITY AND ADVOCACY
You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You may not use Grant Funds to support lobbying activity or to otherwise support

attempts to influence local, state, federal, or foreign legislation. Your strategies and activities, and any materials produced with Grant Funds, must comply with applicable local, state, federal, or foreign lobbying law. You agree to comply with lobbying, gift, and ethics rules applicable to the Project.

OTHER

PUBLICITY

A Party may publicly disclose information about the award of this grant, including the other Party's name, the total amount awarded, and a description of the Project, provided that a Party obtains prior written approval before using the other Party's name for promotional purposes or logo for any purpose. Any public disclosure by You or Your subgrantees, subcontractors, contingent workers, agents, or affiliates must be made in accordance with the Foundation's then-current brand guidelines, which are available at: www.gatesfoundation.org/brandguidelines.

LEGAL ENTITY AND AUTHORITY

You confirm that: (a) You are an entity duly organized or formed, qualified to do business, and in good standing under the laws of the jurisdiction in which You are organized or formed; (b) You are not an individual (i.e., a natural person) or a disregarded entity (e.g., a sole proprietor or sole-owner entity) under U.S. law; (c) You have the right to enter into and fully perform this Agreement; and (d) Your performance will not violate any agreement or obligation between You and any third party. You will notify the Foundation immediately if any of this changes during the term of this Agreement.

COMPLIANCE WITH LAWS

In carrying out the Project, You will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.

COMPLIANCE WITH REQUIREMENTS

You will conduct, control, manage, and monitor the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards ("*Requirements*"). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of Your annual progress report to the Foundation, You must report whether the Project activities were conducted in compliance with all Requirements.

If the Project involves:
a. any protected information (including personally identifiable, protected health, or third-party confidential), You will not disclose this information to the Foundation without obtaining the Foundation's prior written approval and all necessary consents to disclose such information;
b. children or vulnerable subjects, You will obtain any necessary consents and approvals unique to these subjects; and/or
c. any trial involving human subjects, You will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the Foundation in reviewing documents and providing input or funding does not modify Your responsibility for determining and complying with all Requirements for the Project.

RELIANCE

You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

INDEMNIFICATION

If the Project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("*Indemnified Activities*"), You will indemnify, defend, and hold harmless the Foundation and its trustees, employees, and agents ("*Indemnified Parties*") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "*Claims*") arising out of or relating to the acts or omissions, actual or alleged, of You or Your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with

respect to the Indemnified Activities. You agree that any activities by the Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the Foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of Your governmental and sovereign immunities, if any.

INSURANCE
You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted industry standards and as required by law. You will ensure Your subgrantees and subcontractors maintain insurance coverage consistent with this section.

TERM AND TERMINATION

TERM
This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement. The Foundation, in its discretion, may approve in writing any request by You for a no-cost extension, including amending the End Date and adjusting any affected reporting requirements.

TERMINATION
The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS
Any Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation.

MONITORING, REVIEW, AND AUDIT
The Foundation may monitor and review Your use of the Grant Funds, performance of the Project, and compliance with this Agreement, which may include onsite visits to assess Your organization's governance, management and operations, discuss Your program and finances, and review relevant financial and other records and materials. In addition, the Foundation, or its designee, may conduct audits, including onsite audits, at any time during the term of this Agreement, and within four years after Grant Funds have been fully spent. Any onsite visit or audit shall be conducted at the Foundation's expense, following prior written notice, during normal business hours, and no more than once during any 12-month period.

INTERNAL OR THIRD PARTY AUDIT
If during the term of this Agreement You are audited by your internal audit department or by a third party, You will provide the audit report to the Foundation upon request, including the management letter and a detailed plan for remedying any deficiencies observed ("*Remediation Plan*"). The Remediation Plan must include (a) details of actions You will take to correct any deficiencies observed, and (b) target dates for successful completion of the actions to correct the deficiencies.

RECORD KEEPING
You will maintain complete and accurate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Grant Funds have been fully spent. At the request of the Foundation, or its designee, You will make such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used or committed.

SURVIVAL
A Party's obligations under this Agreement will be continuous and survive expiration or termination of this Agreement as expressly provided in this Agreement or otherwise required by law or intended by their nature.

GENERAL

ENTIRE AGREEMENT, CONFLICTS, AND AMENDMENTS

This Agreement contains the entire agreement of the Parties and supersedes all prior and contemporaneous agreements concerning its subject matter. If there is a conflict between this Agreement and the Investment Document this Agreement will prevail. Except as specifically permitted in this Agreement, no modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

NOTICES AND APPROVALS

Written notices, requests, and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the Agreement Summary & Signature Page, or as otherwise directed by the other Party.

SEVERABILITY

Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

ASSIGNMENT

You may not assign, or transfer by operation of law or court order, any of Your rights or obligations under this Agreement without the Foundation's prior written approval. This Agreement will bind and benefit any permitted successors and assigns.

COUNTERPARTS AND ELECTRONIC SIGNATURES

Except as may be prohibited by applicable law or regulation, this Agreement and any amendment may be signed in counterparts, by facsimile, PDF, or other electronic means, each of which will be deemed an original and all of which when taken together will constitute one agreement. Facsimile and electronic signatures will be binding for all purposes.

AMENDMENT 1
to
GRANT AGREEMENT
Investment ID INV-074353

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective November 11, 2024, as amended, and bearing Investment ID INV-074353
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	Date of this email

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		November 2024	$5,393,118.00
	[***]	[***]		
	[***]			
[***]	[***]	[***]		
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	[***]	[***]		
	[***]			
	[***]	[***]		

	[***]	[***]	[***]	Up to $[***]
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	[***]	[***]		
	[***]	[***]		
	[***]		[***]	Up to $[***]
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[***]	[***]	[***]		
Amended Total Grant Amount				**Up to $10,683,142.00**

As provided in the Agreement, signatures are not required.

Exhibit 10.13

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

SUBAWARD AGREEMENT

This Subaward Agreement (this "Agreement") is entered into on October 23, 2024 (the "Effective Date"), by and between Daré Bioscience, Inc. (the "Performer") and the Consortium Management Firm, National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell (the "CMF") (each a "Party" and together the "Parties").

WHEREAS, the CMF wishes to enter into this Agreement with Performer to perform research related to the agreement between CMF and ARPA-H ("Federal Awarding Agency") from which funding for this contract flows ("Prime Agreement") as set forth therein;

WHEREAS, Performer is willing to perform such research in accordance with the terms and conditions set forth herein; and

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to the CMF and Performer.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, terms, provisions and conditions set forth in this Agreement, the parties hereby agree:

1. **Contracting Period**. This Agreement commences on the Effective Date and will remain in effect until the last Statement of Work executed in accordance with this Agreement, the first of which is attached hereto as Attachment 1 (the "Statement of Work") has expired, or unless this Agreement has been terminated pursuant to the terms hereof (hereinafter referred to as the "Contracting Period"). Subsequent statements of work under this Agreement will be in writing and signed by both parties, and will each also constitute a "Statement of Work".

2. **Scope of the Project**

- The Parties agree that the principal purpose of this Agreement is for the CMF and the Performer to provide for a coordinated effort to advance research and technology goals of the Sprint for Women's Health program. The Performer shall be responsible for performance of the work set forth in the Statement of Work (SOW), incorporated in this Agreement as Attachment 1; completed in accordance with the Flowdown Terms incorporated within this Agreement as Attachment 2; and shall submit or otherwise provide all deliverables as required by Attachment 1; provided, *however*, that the CMF acknowledges that achievement or completion of certain deliverables are dependent or conditional upon the actions of third parties, and/or the occurrence of certain events that Performer does not control, and that Performer will not be liable or responsible for failure to meet a specific timeline unless it has failed to use commercially reasonable efforts to do so.

- The Performer shall be paid a fixed amount for each milestone accomplished in accordance with the Schedule of Milestones and Payments set forth in Attachment 1.

- The CMF will have continuous involvement with the Performer through the CMF. The Federal Awarding Agency will also retain a nonexclusive license to obtain access to and to share research results and data, as well as and certain rights in Intellectual Property, all pursuant to and in accordance with the Bayh-Dole Act and Attachment 2. Federal Awarding Agency, the Performer, and the CMF are bound to each other by a duty of good faith and diligent effort in achieving the goals of the Program. Nothing in this Agreement grants the CMF or an third party any right, license, title or interest in or to (i) any information, methods or processes used or developed by or for Performer in or for the provision of Services (including development and delivery of deliverables), or in any documentation, records, data, materials, work product, concepts, information, inventions, improvements, designs, programs, formulas, know-how, or writings related thereto, or in any Intellectual Property Rights or other ownership right in any of the foregoing; (ii) any software, technology, data, information or materials developed or, acquired, or otherwise obtained by Performer, and Intellectual Property Rights or other ownership right in any of the foregoing; or (iii) any ideas, know-how, trade secrets, work products, results, data, information, inventions, works of authorship or other items developed, generated, invented, conceived, reduced to practice or authored by Performer, all of which is "Technology". As between the parties, Performer is the sole and exclusive owner of all Technology and all Intellectual Property Rights relating thereto. Performer reserves all rights not expressly granted herein, and no licenses are granted by implication or estoppel. Technology constitutes Performer's Confidential Information (defined below).

- Additionally, at times Performer will interact with external stakeholders, presenting work and acquiring feedback. Performer should plan to establish and non-disclosure, privacy, and similar agreements with any external stakeholder necessary to discuss project data with them. The CMF will not be party to or responsible for initiating, negotiating or enforcing any such agreement.

- The CMF will comply with the requirements of the Federal Awarding Agency in performing this Agreement and shall devote such working time to the performance of this Agreement as is reasonably necessary for the accomplishment of this Agreement. .

3. **Services**. In accordance with its engagement by the Program, the CMF hereby engages the Performer to provide professional services as set forth in the Statement of Work, and any additional services as may otherwise be set forth in any updated or subsequent executed Statements of Work or similar document (collectively, the "Services"). Upon execution by both Parties, each such Statement of Work is incorporated into and becomes a part of this Agreement. The Performer shall be expected to devote such working time to the performance of the Services as is reasonably necessary for the accomplishment of the Services. In the event of any conflict between this Agreement and a Statement of Work, the terms of the Statement of Work will govern for purposes of such Statement of Work only. Under no circumstances will the CMF owe or pay Performer any fees or other sums that are not in accordance with the Statement of Work issued and signed by CMF.

4. **Contract Type and Value.** This is a firm-fixed price subaward agreement. The Performer shall provide all required tasks in accordance with the Statement of Work at the fixed unit prices specified in Attachment 1.

5. **Invoice and Payment**
   a. As compensation for all Services performed by the Performer during the Contracting Period, the CMF will pay to the Performer the contracting fee as set forth in the Statement of Work and Attachment 1.
      i. **Invoice and Payment.** Performer shall electronically submit an original invoice to the CMF, no later than 30 days after the delivery of Services.
      ii. **Business Expenses.** The CMF, as specified in the applicable Statement of Work, will reimburse at cost, and without indirects or added overhead, necessary, defined,

and reasonable business expenses incurred by the Performer in the performance of the Services under this Agreement during the Contracting Period, subject to submission of adequate substantiation and documentation, and adherence to laws, policies and procedures, and as further described in a Statement of Work ("Reimbursements").

iii. **An invoice must include:**

1. Name and address of the Performer
2. Invoice date and number
3. Statement of Work number and, if applicable, line item number
4. Description, quantity, unit of measure, unit price and extended price of the Services rendered;
5. If applicable, description, quantity, unit of measure, and unit price of the Reimbursements requested accompanied by itemized receipt support documentation;
6. Name and address of official to whom payment is to be sent;
7. Name, title, and phone number of person to notify in event of defective invoice;

iv. **Payment.** Invoices will be paid via Electronic Funds Transfer (EFT) within 30 days after submission, unless otherwise defined on the Statement of Work.

v. If the CMF does not pay invoiced amounts when due then Performer may, without limiting its other available remedies, suspend performance of the Services.

6. **Background Checks & Work Authorizations.** The Performer hereby acknowledges that as part of the engagement process, the CMF may require the Performer to undergo and successfully pass a background check, which includes, but is not limited to searching for the Performer's name on any prohibited work or debarment lists, whether state, federal, or organizational industry or specific and any other background check that may be required. The Performer hereby acknowledges that the proper work permits, visas, and/or authorizations to legally perform its obligations hereunder are necessary for its engagement and that it hereby represents and warrants to having all necessary authorizations.

7. **No Eligibility for Benefits**. The Performer understands and agrees that neither the Performer nor any member of the Performer's family nor other person claiming through the Performer shall be eligible to participate in or receive benefits under any employee benefit plan, program or arrangement maintained by the CMF or any of its Affiliates as a result of the Performer's performance under this Agreement.

8. **Relationship of the Parties**. The CMF and the Performer acknowledge and agree that the Performer is an independent contractor in the performance of Services under this Agreement and that nothing contained in this Agreement is intended to create an employment relationship, partnership or joint venture between the CMF or its Affiliates and the Performer. As an independent contractor, the Performer will work independently on any Statement of Work and will not receive training, assignments, or direction from the CMF, other than as to the goals set forth in the Statement of Work, if any. Performer is free to accept engagements from others during the Contracting Period, so long as those engagements do not prevent the Performer from performing the Services or otherwise violate the Performer's obligations under this Agreement, including the Restricted Activities set forth in Section 12.

9. **Taxes.** As an independent contractor, the Performer shall be solely responsible for unemployment insurance and for the withholding and payment of any and all federal, state and local income taxes and social security and Medicare taxes and other legally-required payments on any sums received from the CMF under this Agreement. The Performer agrees to indemnify and hold harmless the CMF and any of its Affiliates and their respective shareholders, directors, officers, employees, agents, successors and assigns, from any and all losses, costs and expenses, including without limitation attorneys' fees, and any other liabilities incurred by any of the foregoing as a result of the Performer's failure to meet the Performer's obligations under this Section 9.

10. Confidentiality and Related Matters.

a. Confidential Information. The Performer and the CMF each acknowledge that, during the course of providing Services, the CMF, as well as its customers, clients, and Affiliates ("CMF And CMF Stakeholders") and the Performer, may disclose or make available certain Confidential Information, as defined below, to each other. The party receiving Confidential Information from the other party (or, for Performer, from CMF And CMF Stakeholders) ("Receiving Party") agrees not to use or disclose any Confidential Information of the party disclosing Confidential Information ("Discloser") to any third party, except to those persons and entities who (i) need to know the Confidential Information to assist the Receiving Party in connection with this Agreement, or act on the Receiving Party's behalf in relation to this Agreement; AND (ii) are informed by the Receiving Party of the confidential nature of the Confidential Information; AND (iii) are subject to confidentiality duties and obligations that are no less restrictive than the terms and conditions of this Agreement.

The Receiving Party shall not use or disclose any Confidential Information of the Discloser, whether or not obtained in any other past, present or future association with the Discloser or in any of the Statements of Work, for any purpose other than to perform this Agreement, or otherwise in any manner to the detriment of the Discloser, including without limitation, using it for the Receiving Party's own benefit or gain or the benefit or gain of others or for purposes of reverse engineering, disassembling, decompiling or designing around any proprietary services, products, or confidential Intellectual Property. The Receiving Party agrees that these restrictions shall continue to apply for a period of five years after the Contracting Period ends, regardless of the reason. The Receiving Party will protect and safeguard the confidentiality of all such Confidential Information with at least the same degree of care that the Receiving Party would protect its own Confidential Information, but in no event with less than a commercially reasonable degree of care.

Additionally, Performer may be expected to sign a non-disclosure agreement as required by Awarding Party of Prime Contract.

The Receiving Party agrees to furnish prompt notice to the Discloser of any required disclosure of the Discloser's Confidential Information sought pursuant to subpoena, court order or any other legal process or requirement, and agrees to provide the Discloser a reasonable opportunity to seek protection of the Confidential Information prior to any such disclosure, unless precluded by applicable law. Subject to the prior sentence, the Receiving Party may disclose the Discloser's Confidential Information to the extent required by a court or other governmental authority, in which case it shall reasonably cooperate with the Discloser, at Discloser's expense and request, to resist or limit the disclosure.

The Receiving party shall return all of the Discloser's Confidential Information in the Receiving Party's possession or control within thirty (30) days of the Discloser's written request therefor.

b. Notice under the United States Defend Trade Secrets Act of 2016 ("DTSA" at 18 U.S.C. §1832 et seq.). The DTSA provides immunity from liability for the confidential disclosure of a trade secret to the government or in a court filing under certain conditions. (18 U.S.C. §1833.) Specifically, "an individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law, or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal." Additionally, "an "individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (X) files any document containing the trade secret under seal, and (Y) does not disclose the trade secret, except pursuant to court order."

11. Intellectual Property. During the term of this Agreement, the Performer shall promptly inform the CMF, in confidence, all Intellectual Property for which Federal Awarding Agency retains a license

pursuant to and in accordance with the Bayh-Dole Act (but Performer is not obligated to divulge proprietary information to the CMF). Performer has the responsibility of taking all steps necessary to comply with the Bayh-Dole Act if and when it applies.

12. **Restricted Activities**. The Performer acknowledges and agrees that the following restrictions on the Performer's activities are necessary to protect the goodwill, Confidential Information, trade secrets and other legitimate interests of the CMF or its Affiliates:
    a. **Conflicts of Interest Prohibited.** The Performer agrees that, during the Contracting Period, the Performer will not undertake any outside activity that constitutes a conflict of interest or otherwise makes Performer incapable of meeting its performance requirements of the Services.

13. **Enforcement**. In signing this Agreement, the Performer gives the CMF assurance that the Performer has carefully read and considered all the terms and conditions of this Agreement, including the restraints imposed on the Performer under Sections 10, 11 and 12 hereof. The Performer agrees without reservation that these restraints are necessary for the reasonable and proper protection of the CMF and its Affiliates, and that each and every one of the restraints is reasonable in respect to subject matter, length of time and geographic area. Each Party agrees that, were it to breach any of the covenants contained in Sections 10, 11 and 12, the damage to the other Party could be irreparable and that the other Party, in addition to any other remedies available to it, shall be entitled to seek preliminary and permanent injunctive relief against any breach or threatened breach by such Party of any of those covenants, without having to post bond, together with an award of its reasonable attorney's fees incurred in enforcing its rights hereunder pursuant to an action in which it is the prevailing party. The Performer and the CMF further agree that, in the event that if any provision of this Agreement is determined by any court of competent jurisdiction to be unenforceable, that provision shall be deemed severed.

14. **Disclaimer of Warranties.**
    a. **CMF.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, THE CMF (INCLUDING ITS AFFILIATES, DIRECTORS, OFFICERS, EMPLOYEES, AGENTS, CONTRACTORS, SUCCESSORS, AND ASSIGNEES, (COLLECTIVELY, THE "CMF PARTIES") DISCLAIMS, TO THE MAXIMUM EXTENT PERMITTED BY LAW, ALL CONDITIONS, REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, ANY IMPLIED WARRANTY IN RELATION TO THE SERVICES, ASSIGNMENTS, OR THIS ENGAGEMENT. WITHOUT LIMITING THE FOREGOING, THE CMF PARTIES MAKE NO REPRESENTATION, WARRANTY, OR GUARANTY AS TO THE SAFETY OF THE STATEMENT OF WORK OR WORKING CONDITIONS OF A STATEMENT OF WORK LOCATION. THE PERFORMER ACKNOWLEDGES THAT THE STATEMENT OF WORK MAY INVOLVE CERTAIN RISKS, INCLUDING, BUT NOT LIMITED TO, POTENTIAL EXPOSURE TO AND ILLNESS FROM INFECTIOUS DISEASE, INCLUDING, BUT NOT LIMITED TO INFLUENZA AND COVID-19. THE PERFORMER KNOWINGLY AND FREELY ASSUMES ALL SUCH RISKS, BOTH KNOWN AND UNKNOWN.

    b. **PERFORMER.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, PERFORMER DISCLAIMS, TO THE MAXIMUM EXTENT PERMITTED BY LAW, ALL OTHER CONDITIONS, REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY IN RELATION TO THE SERVICES, ASSIGNMENTS, OR THIS ENGAGEMENT, AND WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15. **Indemnification**.
    a. **CMF Rights.** The Performer shall indemnify, defend and hold harmless the CMF and any of its Affiliates and each of their respective shareholders, officers, directors, employees, agents, successors and permitted assigns from and against any and all third party claims and actions (each a "Claim") brought against any of such persons or entities, and pay all losses, liabilities, damages, expenses, interest, awards, penalties, fines, or costs of whatever kind including reasonable attorneys' fees,

payable to such third party pursuant to such Claim (collectively, "Losses") to the extent arising out of or relating to (i) Performer's gross negligence or willful misconduct in performing this Agreement; (ii) Performer's material breach of this Agreement; (iii) Performer's non-compliance with any applicable law in performing Services; and (iv) any bodily injury, death of any person, or damage to real or tangible personal property caused by the negligent acts or omissions of the Performer.

b. Performer Rights. The CMF shall indemnify, defend and hold harmless the Performer and its shareholders, officers, directors, employees, agents, successors and permitted assigns from and against any and all Claims brought against any of such persons or entities, and pay all corresponding Losses to the extent arising out of or relating to (i) CMF's gross negligence or willful misconduct in performing this Agreement; (ii) CMF's material breach of this Agreement; (iii) CMF's non-compliance with any applicable law in performing this Agreement.

c. Indemnification Procedures. The Party seeking indemnification ("Indemnified Party") of a Claim from the other Party ("Indemnifying Party") under this Section 15 shall notify the Indemnifying Party promptly upon becoming aware of the Claim and shall permit the Indemnifying Party to control the defense and settlement of the Claim, and shall reasonably cooperate with the Indemnifying Party in such efforts. The Indemnified Party may not consent to the settlement or entry of judgment in a Claim without the Indemnifying Party's prior written consent. The Indemnified Party may participate in the defense of the Claim with its own counsel at its own expense. The Indemnifying Party will not consent to the settlement or entry of judgment in a Claim that does not unconditionally release the Indemnified Party, or that admits any liability on behalf of the Indemnified Party.

The Indemnified Party may assume, at its sole option, control of the defense, appeal, or settlement of any Claim if the Indemnifying Party fails to defend such Claim in breach of its obligations under Section 15(a) or Section 15(b) (as applicable) by sending written notice of the assumption to the Indemnifying Party and at Indemnifying Party's sole and reasonable cost and expense, the settlement or defense thereof. If the Indemnified Party assumes control of the defense under this Section 15(c), Indemnifying Party shall reimburse Indemnified Party promptly and periodically for the costs properly incurred in defending against the Indemnified Claim (including reasonable attorneys' fees and expenses); and remain responsible to Indemnified Party for any Losses indemnified under this Section 15.

16. Limitation of Liability. IN NO EVENT SHALL CMF OR ANY OF ITS AFFILIATES NOR PERFORMER BE LIABLE TO EACH OTHER OR TO ANY THIRD PARTY FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR ENHANCED DAMAGES, OR LOST PROFITS OR REVENUES, ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH THIS AGREEMENT, REGARDLESS OF (A) WHETHER SUCH DAMAGES WERE FORESEEABLE, (B) WHETHER OR NOT SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND (C) THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT OR OTHERWISE) UPON WHICH THE CLAIM IS BASED.

IN NO EVENT SHALL CMF'S OR ANY OF ITS AFFILIATES' OR PERFORMER'S AGGREGATE LIABILITY FOR DIRECT DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EXCEED THE TOTAL OF THE AMOUNTS PAID AND PAYABLE TO THE PERFORMER PURSUANT TO THIS AGREEMENT IN THE SIX MONTH PERIOD PRECEDING THE EVENT GIVING RISE TO THE CLAIM; *PROVIDED, HOWEVER,* THAT IF SUCH AMOUNT IS LESS THAN $500,000, THEN EACH PARTY'S MAXIMUM AMOUNT OF LIABILITY FOR DIRECT DAMAGES SHALL INSTEAD NOT EXCEED $500,000.

Damages caused by a Party's breach of Section 10, and amounts payable by a Party pursuant to its indemnification obligations in Section 9 and 15, and fees payable by CMF to Performer in accordance with Section 5, are not limited by this Section 16.

17. Inspection and Acceptance. The Parties acknowledge that the Federal Awarding Agency may inspect and otherwise evaluate the Services or Deliverables at any reasonable time and place, but such review or approval shall not relieve either Party from its obligations set forth in this Agreement.

If the CMF believes that any Services do not conform to the requirements of the applicable Statement of Work, and informs Performer promptly upon becoming aware of such nonconformity, then the Parties will work together in good faith to discuss and address the alleged nonconformity.

Acceptance of the items or services is conditioned upon final acceptance by CMF's Federal Awarding Agency. Payments, including final payment, shall not constitute acceptance, nor does any payment or final acceptance release Performer from any warranty hereunder.

Performer bears the risk of loss for items or Services until final acceptance thereof by the Federal Awarding Agency. Unless specified elsewhere in this contract, including Section 11 and Attachment 2, title to items furnished under this contract shall pass to the Federal Awarding Agency upon acceptance, regardless of when or where the Federal Awarding Agency takes physical possession.

18. Warranty. Performer warrants that all Services performed under this Agreement will be performed with the standard of a fully qualified professional, and be performed in strict compliance with any applicable regulatory or international standards specified in the Statement of Work for this Agreement. Any services corrected or re-performed will be covered by this warranty. The CMF's sole and exclusive remedy for breach of this warranty, and the Performer's sole liability for breach of this warranty, is for Performer to use commercially reasonable efforts to re-perform the nonconforming Services; *provided, however*, that Performer acknowledges that if Federal Awarding Agency refuses payment for a portion or the entirety of the milestone payment or a portion or the entirety of the contractual payment, then CMF is not obligated to make a corresponding payment to the Performer

19. Performance Restriction. Subject to the other provisions of this Section 19, Performer is restricted from engaging in any scope of work activity that involves human subject or animal subject research. Likewise, Performer may not use or submit invoice for any award funding to carry out any human subject or animal subject research until this written notice is received. Failure to obtain appropriate human or animal subject research approval may result in termination of agreement.

For clarity, no research involving human subjects may occur, and individuals shall not be enrolled in such research, without prior approval by the Office for Human Research Protection (OHRP) of an assurance to comply with the requirements of 45 CFR Part 46 to protect human research subjects. If funding was provided on the understanding that human subject research would eventually occur with funding provided, the awardee institution bears the ultimate responsibility for protecting human subjects under the award. Compliance for all performance sites must be ensured by the awardee. The Performer must 1) obtain a Federal-wide Assurance (FWA) of Protection for Human Subjects from the Office for Human Research Protection (OHRP), 2) obtain initial and continuing approval (if required) of the research by an appropriately constituted and registered Institutional Review Board (IRB), and 3) submit the full IRB approved package (including protocol, IRB approval letter, any required training certificates, etc.). For instructions on registering IRBs, obtaining FWAs, and completing Human Subjects Education requirements, see the OHRP website at: https://www.hhs.gov/ohrp.

In order to remove this restriction, Performer shall submit evidence of the required FWA and IRB approval package to the PM and BID. When all of the required documentation has been reviewed and approved by the Government, the Agreements Officer (AO) of CMF will lift the restriction via written notification.

20. Termination of Agreement and Related Matters.

a. Termination for Convenience.

i. If the Prime Agreement is terminated this agreement will automatically terminate. CMF shall provide prompt notice of termination of the Prime Agreement.

ii. If the Prime Agreement is materially changed, through no fault of the CMF, in a way that would materially adversely affect CMF financially, then CMF may, at its option, terminate this agreement upon 30 days notice.

iii. Additionally, if the Parties have experienced significant, material, chronic and/or regular disagreements or disputes with respect to Performer's performance under this Agreement, and if such matters cannot be resolved amicably after good faith discussion and escalation, and if as a result of such issues, either Party wishes to terminate this Agreement, then CMF shall have the option of terminating this Agreement. Subject to the terms of this Agreement, the Performer shall be paid only for the Services performed up to the date of termination.

b. Termination for Cause. Each Party may terminate this Agreement for cause upon notice in the event of any material breach of this Agreement or Statement of Work by the other Party that is not cured within thirty (30) days of notice of such breach. In the event of termination for cause, the CMF shall not be liable to the Performer for any amount for supplies or services not accepted by the Federal Awarding Agency , and termination does not prejudice either Party's other available rights and remedies provided by law.

21. Conflicting Agreements.

a. The Performer hereby represents and warrants that it has full power and authority to perform its obligations under this Agreement and that the execution of this Agreement and the performance of the Performer's obligations hereunder will not breach or be in conflict with any other agreement to which the Performer is a party or is bound and that the Performer is not now subject to any covenants against competition or similar covenants or any court order or other legal obligation that conflict with the performance of the Performer's obligations hereunder. The Performer agrees that during the Contracting Period Performer will not enter into any agreement or assume any legal obligation that conflicts with the Performer's obligations hereunder. The Performer shall not disclose to or use on behalf of the CMF or any of its Affiliates any proprietary information of any third party without such party's consent. The Performer hereby represents and warrants that when signed by the Performer, this Agreement constitutes a valid and legally binding obligation on it that is enforceable in accordance with the terms of this Agreement.

b. The CMF hereby represents and warrants that it has full power and authority to perform its obligations under this Agreement and that the execution of this Agreement and the performance of its obligations hereunder will not breach or be in conflict with any other agreement to which it is a party or is bound and that the CMF is not now subject to any covenants against competition or similar covenants or any court order or other legal obligation that conflict with the performance of the CMF's obligations hereunder. The CMF agrees that during the Contracting Period the CMF will not enter into any agreement or assume any legal obligation that materially impairs its ability to meet the CMF's obligations hereunder. The CMF shall not disclose to or use on behalf of Performer any proprietary information of any third party without such party's consent. The CMF hereby represents and warrants that when signed by the CMF, this Agreement constitutes a valid and legally binding obligation on it that is enforceable in accordance with the terms of this Agreement.

22. Definitions. Words or phrases which are initially capitalized or are within quotation marks shall have the meanings provided in this Section and as provided elsewhere herein. For purposes of this Agreement, the following definitions apply:

a. "Affiliates" means all persons and entities directly or indirectly controlling, controlled by or under common control with the named entity, where control may be by management authority, equity interest or otherwise.

b. "Confidential Information" means any and all non-public, confidential, or proprietary information that is not generally known by others, disclosed before, on, or after the Effective Date, by the

Discloser, including such information that the Discloser has received, or may receive hereafter, belonging to customers or others with any understanding, express or implied, that the information would not be disclosed, and any such information disclosed to the Receiving Party in any of Statement of Work, whether disclosed orally or disclosed or accessed in written, electronic or other form or media, and whether or not marked, designated, or otherwise identified as "confidential," including, without limitation:

i. information disclosed in any Statement of Work or by the Discloser or any of its Affiliates relating to past, present, and future business affairs including, without limitation, finances, customer information, supplier information, products, services, financial results, records and budgets;

ii. unpatented inventions, ideas, methods, and discoveries, trade secrets, know-how, unpublished patent applications, and other confidential Intellectual Property;

iii. designs, specifications, documentation, components, source code, object code, images, icons, audiovisual components, and objects, schematics, drawings, protocols, processes, and other visual depictions, in whole or in part, of any of the foregoing;

iv. third-party confidential information (including, without limitation, any personally identifiable information) included with, or incorporated in, any information provided by the Discloser to the Receiving Party;

v. other information that would reasonably be considered non-public, confidential, or proprietary given the nature of the information and the Parties' businesses; and

vi. notes, analyses, compilations, reports, forecasts, studies, samples, data, statistics, summaries, interpretations, and other materials prepared by or for the Receiving Party that contain, are based on, or otherwise reflect or are derived, in whole or in part, from any of the foregoing.

Except as required by applicable federal, state, or local law or regulation, the term "Confidential Information" as used in this Agreement shall not include information that: at the time of disclosure is, or thereafter becomes, generally available to and known by the public other than as a result of, directly or indirectly, any breach of this Agreement by the Receiving Party; at the time of disclosure is, or thereafter becomes, available to the Receiving Party on a non-confidential basis from a third-party source, provided that such third party is not and was not prohibited from disclosing such Confidential Information to the Receiving Party by any legal, fiduciary, or contractual obligation; was known by or in the possession of the Performer, as established by documentary evidence, prior to being disclosed by or on behalf of the Discloser pursuant to this Agreement; or was or is independently developed by the Receiving Party, as established by documentary evidence, without reference to or use of, in whole or in part, any of the Confidential Information disclosed by or on behalf of the Discloser.

c. "Intellectual Property" means inventions, discoveries, developments, compositions, works, concepts and ideas (whether or not patentable or copyrightable or constituting trade secrets) conceived, made, created, developed or reduced to practice (whether alone or with others, whether or not during normal business hours or on or off premises) in performance of the Services.

23. Assignment and Subcontracting. Neither the CMF nor the Performer may make any assignment of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other; provided, however,

a. the CMF may assign its rights and obligations under this Agreement without the consent of the Performer in the event that the CMF shall hereafter effect a reorganization, consolidate with, or merge into, an Affiliate or any third Person or transfer all or substantially all of its properties, stock, or assets to an Affiliate or third Person.

b. that neither party can unreasonably withhold, condition or delay its consent to the assignment of this Agreement.

This Agreement shall inure to the benefit of and be binding upon the CMF and the Performer, and their permitted respective successors, executors, administrators, and assigns. The Performer shall not subcontract any portion of its duties under this Agreement without the prior written consent of the CMF, not to be unreasonably withheld, conditioned or delayed.

24. **Severability**. If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

25. **Waiver**. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of either Party to require the performance of any term or obligation of this Agreement, or the waiver by either Party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

26. **Notices**. Any and all notices, demands and other formal or legal communications provided for by this Agreement shall be in writing and shall be effective when delivered in person, consigned to a reputable national courier service or deposited in the United States mail, postage prepaid, registered or certified, or emailed (with receipt confirmed) and addressed as follows:

Performer:

Daré Bioscience, Inc.
3655 Nobel Drive, Suite 260
San Diego, CA 92122
Attention: Sabrina Johnson, Chief Executive Officer
sjohnson@darebioscience.com

CMF:

Chris Desrosiers
VentureWell
100 Venture Way
Hadley, MA 01035
[***]

27. **Entire Agreement and Amendment.** This Agreement, together with the SOW and Attachments, constitutes the entire agreement between the Parties and supersedes all prior communications, agreements and understandings, written or oral, with respect to the subject matter herein.

28. **Headings and Counterparts.** The headings and captions in this Agreement are for convenience only and in no way define or describe the scope or content of any provision of this Agreement. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument. This Agreement and a Statement of Work may be modified or amended only by a written agreement signed by both Parties.

29. **Governing Law and Consent to Jurisdiction.** This Agreement shall be construed and enforced under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without regard to any conflict of laws principles to the contrary.

30. **Force Majeure**. Performer will be excused from performance for any period during which, and to the extent that it or its subcontractor(s) is prevented from performing any obligation or service, in whole or in

part, as a result of causes beyond its reasonable control such as acts of nature, acts of war or terror, infrastructure delay or failure, governmental orders, and the effects of epidemic or pandemic. For the avoidance of doubt, the CMF is not obligated to pay the Performer for Services that are not performed as a result of such cause(s).

31. **Dispute Resolution.** The Parties agree to attempt initially to solve all claims, disputes or controversies arising under, out of or in connection with this Agreement by conducting good faith negotiations. If the Parties are unable to settle the matter between themselves, the matter shall thereafter be resolved by final and binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any arbitration hereunder shall be conducted under the rules of the American Arbitration Association by a single arbitrator chosen in accordance with such rules. Any such arbitration shall be held in Boston, Massachusetts. The prevailing party in any such arbitration shall be entitled to recover from the other party, in addition to any other remedies, all reasonable costs, reasonable attorneys' fees and other expenses incurred by such prevailing party. The arbitration award is enforceable in any court having jurisdiction.

32. **Survival**. Provisions of this Agreement shall survive any termination if so provided herein or if necessary or desirable to accomplish the purposes of other surviving provisions, including without limitation, the obligations of the Performer under Section 8,10, 11,13, 14, 15 &16 hereof and any liability for any breach thereof, whether during the Contracting Period or thereafter, and the CMF's payment obligations.

33. **Changes**. Each Party agrees that upon the written request of the other Party, such Party will negotiate in good faith with the other Party relative to amendments to this Agreement, as the other Party may reasonably request and deem necessary in order to comply with the provisions of the Prime Agreement. If any such amendment to this Agreement, which the Parties shall enter into in their respective sole discretion, causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this Agreement, Performer and CMF agree to negotiate an equitable adjustment to the applicable Statement of Work in good faith.

34. **Compliance with Laws.** The Performer hereby acknowledges and agrees to comply with all applicable laws, as may be amended from time to time during the Contracting Period, in performing Services, including but not limited to, the following
    a. **Non-Discrimination Statutes**. The Performer agrees to comply with the provisions of Title VI of the Civil Rights Act of 1964 [42 USC §§ 2000d et seq.], Title IX of the Education Amendments of 1972 [20 USC §§ 1681 et seq.], the Rehabilitation Act of 1973 [29 USC § 794], the Age Discrimination Act of 1975 [42 USC §§ 6101 et seq], Equal Employment Opportunity [E.O. 11246], Limited English Proficiency (LEP) [E.O. 13166] and all regulations and policies issued by U.S. Department of State pursuant to these statutes. Specifically, in accordance with these statutes, regulations and policies, no person on the basis of race, color, national origin, sex, disability, or age shall be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under the award.
    b. **Compliance with laws unique to Government contracts.** Performer agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.
    c. **Debarment and Suspension (E.O.s 12549 and 12689).** The Performer represents and warrants that it is not listed on the General Services Administration's List of Parties Excluded from Federal Procurement or Nonprocurement Programs in accordance with E.O.s 12549 and 12689, "Debarment and Suspension." This list contains the names of parties debarred, suspended, or otherwise excluded by agencies, and contractors declared ineligible under statutory or regulatory authority other than E.O. 12549. If the Order exceeds the small purchase threshold, the Performer shall provide to CMF the required certification regarding its exclusion status and that of its principal employees.

IN WITNESS WHEREOF, this Agreement has been executed as a sealed instrument by the Parties' duly authorized representatives, effective as of the Effective Date.

Daré Bioscience, Inc.:	National Collegiate Inventors and Innovators Alliance (NCIIA), d/b/a VentureWell:
By: /s/ Sabrina Johnson	By: /s/ Chris Desrosiers
Name: Sabrina Johnson	Name: Chris Desrosiers
Title: CEO	Title: Vice President, Finance & Administration
10/17/2024	10/22/2024

ATTACHMENT 1: Statement of Work (SOW)

STATEMENT OF WORK
for
"Novel at-home strategy to control the virus that causes cervical cancer to ultimately prevent women from becoming patients"

1.0 BACKGROUND

One of the women's health issues that Daré Bioscience has been working to address is cervical cancer, a pressing health challenge both in the U.S. and abroad. Daré has approached this problem from the mindset that intervening once women have cancer is too late; we want to ultimately prevent women from becoming cancer patients in the first place. This can be done by addressing the most significant risk factor for progression to cervical cancer, which is persistent infection with high-risk human papillomavirus (hrHPV).

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Essentially all cervical cancers worldwide are caused by infection with one of 14 carcinogenic, or "high-risk" HPV types (hrHPV). Persistent hrHPV infection is defined as testing positive for high-risk HPV type(s) at consecutive timepoints for at least 12 months. High-risk HPV can progress to cervical cancer through a series of lesions (abnormal cell growth on the cervix) called cervical intraepithelial neoplasia (CIN); there is no way to know who will develop cancer or other health problems from HPV infection. In the U.S. alone, approximately 25 million women (15.6% of the female population) have persistent hrHPV, of which 14,000 will be newly diagnosed with cervical cancer this year, and more than 4,000 will die from the disease in 2024.

The current standard of care for hrHPV is "watchful waiting," where patients are monitored to determine if and when there is progression to CIN. It is challenging, especially in lower resource settings, to ensure that women undergo the frequent, invasive, burdensome, and costly screening measures necessary to detect progression from hrHPV to CIN, or to ensure that women receive the surgical intervention (a Loop Electrosurgical Excision Procedure, or LEEP, which uses a small, electrically charged wire loop to remove cervical tissue) to address CIN before it becomes cervical cancer. This could be avoided by preventative health measures such as therapeutic strategies that directly target hrHPV infection before it can progress to CIN and cancer.

Recognizing this urgent need, Daré is developing a product that already has proof of concept and with ARPA-H's support is well-positioned to progress quickly to regulatory approval as the first treatment for clearance of persistent hrHPV infection. The product, called DARE-HPV, is a soft gel vaginal insert containing two antiretroviral drugs, lopinavir and ritonavir, which are well-known and already have demonstrated safety. The combination of these drugs *corrects the underlying cause* of persistent hrHPV infection by disrupting the life cycle of the virus and restoring the normal cellular processes that safeguard against persistent infection and CIN, and ultimately cervical cancer. The intended use of DARE-HPV is a single dose (one capsule) inserted into the vagina once daily for 21 days.

The availability of a commercial DARE-HPV product is expected to: (1) reduce the incidence and mortality of cervical cancer; (2) decrease the healthcare burden and costs associated with long-term management of hrHPV infections and the resulting diseases (CIN and cervical cancer), which are more costly than infection management; (3) reduce the stress and anxiety associated with the current ambiguous "watchful waiting" approach for hrHPV, thereby increasing quality-of-life; (4) improve health equity - since there is a disparity in the incidence and mortality of cervical cancer among different socioeconomic groups, self-administered home-use DARE-HPV will likely contribute to reducing these disparities; and (5) reduce hrHPV transmission, broadly improving public health. This represents a transformative step forward for women, too many of whom die from cervical cancer each year in the U.S. and globally, a condition that is largely preventable.

2.0 TECHNICAL REQUIREMENTS:

Work has already been completed to demonstrate the safety and effectiveness of DARE-HPV for clearance of hrHPV, and to optimize the ratio of the two antiviral drugs in the product to ensure maximal effectiveness. The drugs used in DARE-HPV, lopinavir and ritonavir, were FDA approved as a combination drug in 2000 for HIV treatment (Kaletra®) and are both now off-patent. With FDA concurrence, we intend seek regulatory approval for DARE-HPV through the 505(b)2 New Drug Application (NDA) pathway, with Kaletra® as the previously approved, "listed" drug. The 505(b)2 NDA pathway is a streamlined NDA process that will allow us to apply for approval without having to repeat all of the drug development work done for Kaletra® approval. This pathway is advantageous

because it is potentially faster and less costly than the full 505(b)1 NDA pathway, allowing DARE-HPV to reach women more quickly [***].

However, because there are currently no FDA-approved treatments to clear persistent hrHPV infection (or CIN), we need to accomplish the following critical objectives to establish a clear path towards FDA approval and commercialization: (1) align with FDA on the clinical study endpoints to demonstrate that DARE-HPV effectively clears hrHPV [***]; and (2) conduct a clinical study in the U.S. in which we demonstrate the validity of the DARE-HPV approach which represents a change to the standard of care and the setting in which care is provided (at home vs. provider office). Our proposed work involves regulatory interactions with FDA to present the data we have generated thus far for DARE-HPV and determine what additional data are needed for the 505(b)2 NDA pathway. Given that there are no FDA guidelines for a vaginal antiviral treatment for hrHPV infection, it is crucial to work closely and collaboratively with the FDA to define how treatments in this new category will be regulated. One of the most important aspects of this is the measures used to determine the effectiveness of the new potential treatments. Once effectiveness measures (endpoints) have been aligned on with FDA, a clinical study is necessary to demonstrate that treatment with DARE-HPV results in successful clearance of hrHPV and improves health outcomes compared to the current "watchful waiting" standard of care.

[***]

DESCRIPTION OF TECHNICAL TASKS, MILESTONES, AND DELIVERABLES

[***]

3.0 DELIVERY SCHEDULE:

[***]

SCHEDULE OF TECHNICAL TASKS, MILESTONES, AND DELIVERABLES

[***]

4.0 LAUNCHPAD PROGRAM REQUIREMENTS

[***]

5.0 PAYMENT MILESTONE SCHEDULE

[***]

6.0 PERIOD OF PERFORMANCE: The period of performance for this statement of work is 24 months.

7.0 PLACE OF PERFORMANCE: The primary place of performance shall be 3655 Nobel Drive, Suite 260, San Diego, CA 92122. Travel to in-person events (Location TBD) is also expected during performance of this agreement.

REPORT REQUIREMENTS

[***]

ATTACHMENT 2: Flowdown Terms

FOREIGN ACCESS TO TECHNOLOGY

This Article shall remain in effect during the term of the Agreement and for three (3) years thereafter.

A. **General**

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, the provisions of the International Traffic in Arms Regulations (22 C.F.R. Part 120, et seq.), the Department of Commerce's Export Administration Regulations (15 C.F.R. Part 730, et seq.) or other statutory or regulatory requirements governing foreign access controls.

B. **Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions**

1. In order to promote the interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in subparagraphs B.2, B.3, and B.4 of this Article shall apply to any transfer of Technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology. Transfers do not include:

    a. Sales of products or components; or

    b. Licenses of software or documentation related to sales of products or components; or

    c. Transfer to foreign subsidiaries of the performer for purposes related to this Agreement; or

    d. Transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

2. The Performer shall provide timely notice to ARPA-H of any proposed transfers from the Performer of Technology developed by the Performer under this Agreement to Foreign Firms or Institutions. If ARPA-H determines that the transfer may have adverse consequences to the interests of the United States, the Performer, its vendors, and ARPA-H shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer, but which provide substantially equivalent benefits to the Performer.

3. In any event, the Performer shall provide written notice to the Agreements Officer's Representative (AOR) and the AO of any proposed transfer to a Foreign Firm or Institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within thirty (30) calendar days of receipt of the Performer's written notification, the AO shall advise the Performer whether it consents to the proposed transfer. In cases where ARPA-H does not concur or sixty (60) calendar days after receipt and ARPA-H provides no decision, the Performer may utilize the procedures under Article 6, Disputes. No transfer shall take place until a decision is rendered.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by ARPA-H takes place, the Performer shall (a) refund to ARPA-H funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice, or to have practiced on behalf of the United States, the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the Performer shall provide written confirmation of such licenses.

C. **Lower Tier Agreements**

The Performer shall include this Article, suitably modified, to identify the Parties, in all subcontracts, subagreements, lower tier agreements, Initiative OTs, or CPOs, regardless of tier.

PUBLIC RELEASE OR DISSEMINATION OF INFORMATION

There are no publication restrictions. The Performer and any subcontractors/subrecipients may publish and make public communications and presentations regarding the results of its/their work under this Agreement without prior written approval from the government. Additionally, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

> *"This research was funded in part by the U.S. government. The views and conclusions contained in this document are those of the author(s) and should not be interpreted as representing the official policies, either expressed or implied, of the U.S. government."*

PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT

A. **Definitions. As used in this Article**

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

1. Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);
2. For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);
3. Telecommunications or video surveillance services provided by such entities or using such equipment; or
4. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means

1. Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, C.F.R;

2. Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, C.F.R., and controlled-
    a. Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or
    b. For reasons relating to regional stability or surreptitious listening;
3. Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, C.F.R. (relating to assistance to foreign atomic energy activities);
4. Nuclear facilities, equipment, and material covered by part 110 of title 10, C.F.R. (relating to export and import of nuclear equipment and material);
5. Select agents and toxins covered by part 331 of title 7, C.F.R., part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or
6. Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. § 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

B. **Prohibition**

1. For purposes of this Agreement, Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) applies and prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Performer is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at Paragraph C of this Article applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

2. Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at Paragraph C of this Article applies or the covered telecommunication equipment or services are covered by a waiver

described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a federal agreement.

C. **Exceptions. This Article does not prohibit the Performer from providing**

1. A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

2. Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

D. **Reporting requirement**

1. In the event the Performer identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during agreement performance, or the Performer is notified of such by a subcontractor at any tier or by any other source, the Performer shall report the information in Paragraph D.2. of this Article to the AO, unless elsewhere in this Agreement are established procedures for reporting the information.

2. The Performer shall report the following information pursuant to Paragraph D.1. of this Article

    a. Within one (1) business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.
    b. Within ten (10) business days of submitting the information in Paragraph D.2.a. of this Article: any further available information about mitigation actions undertaken or recommended. In addition, the Performer shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

E. **Lower Tier Agreements**

The Performer shall insert the substance of this Article, including Paragraph E. of this Article and excluding Paragraph B.2. of this Article, in all subcontracts, subagreements, Initiative OTs, CPOs, and other contractual instruments, including for the acquisition of commercial products or commercial services.

PROHIBITION ON A BYTEDANCE COVERED APPLICATION

A. **Definitions. As used in this Article**

Covered application means the social networking service TikTok or any successor application or service developed or provided by ByteDance Limited, or an entity owned by ByteDance Limited.

Information technology, as defined in 40 U.S.C. 11101(6)—

Means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a contractor under a contract with the executive agency that requires the use—

Of that equipment; or

Of that equipment to a significant extent in the performance of a service or the furnishing of a product;

Includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources; but

Does not include any equipment acquired by a Federal contractor incidental to a Federal contract.

B. **Prohibition**

Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the No TikTok on Government Devices Act, and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated February 27, 2023, "No TikTok on Government Devices" Implementation Guidance, collectively prohibit the presence or use of a covered application on executive agency information technology, including certain equipment used by Federal contractors. For purposes of this Agreement, the Performer is prohibited from having or using a covered application on any information technology owned or managed by the Government, or on any information technology used or provided by the Performer under this Agreement, including equipment provided by the Performer's employees; however, this prohibition does not apply if the AO provides written notification to the Performer that an exception has been granted in accordance with OMB Memorandum M-23-13.

C. **Lower Tier Agreements**

The Performer shall insert the substance of this Article, including this paragraph (c), in all subcontracts, subagreements, Initiative OTs, and CPOs, including for the acquisition of commercial products or commercial services.

HUMAN SUBJECT RESEARCH

A. Protection of Human Subjects

1. The Performer agrees that any engagement in human subjects involved in research under this Agreement shall occur in accordance with 45 CFR Part 46 and the Performer's current Federal-wide Assurance (FWA) on file with the HHS Office for Human Research Protections (OHRP). Similarly, Performer agrees that any human subjects research under this Agreement shall occur in accordance with any applicable law, regulation, or rule enforced by the U.S. Food and Drug Administration including, but not limited to 21 CFR 50, 56, 312, and 812. The Performer further agrees to provide certification to the AOR that an overseeing Institutional Review Board has reviewed and approved, as required by applicable law and regulation, any human subjects research occurring under this Agreement prior to the engagement in such research.

2. The Performer shall retain full responsibility for the performance of all work and services involving human subjects research under this Agreement in accordance with the terms of this award.

3. If at any time during the performance of this Agreement, the AO determines that the Performer is not in compliance with any of the requirements and/or standards stated in paragraphs 1 or 2 of this Article, the AO may immediately suspend, in whole or in part, work and further payments under this Agreement until the Performer corrects the non-compliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Performer fails to complete corrective action within the period designated in the AO's written notice of suspension, the AO may terminate this Agreement in a whole or in part.

B. Human Materials

1. The acquisition and supply of all human specimen material (including fetal material) used under this Agreement shall be obtained by the Performer in full compliance with applicable federal, state, and local laws and no undue inducements (monetary or otherwise) will be offered to any person to influence their donation of human material.

2. The Performer shall provide written documentation that all human materials obtained because of engagement in non-exempt research involving human subjects conducted under this Agreement, or by subawards identified under this Agreement, were obtained after acceptance and approval by the Office for Human Research Protections (OHRP) of the engaged entity's FWA. This restriction applies to all collaborating sites, whether domestic or foreign, and compliance must be ensured by the Performer.

3. The Performer shall provide the AO with a properly completed "*Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption,*" OMB Form 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained and constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form, provided that it contains the information required by the OMB Form 0990-0263.

C. Research Involving Human Fetal Tissue

All research involving human fetal tissue shall be conducted in accordance with 42 U.S.C. 289g-2 and 45 CFR 46.206. Additionally, all research involving the transplantation of human fetal tissue shall be conducted in accordance with 42 U.S.C. 289g-1, and for such research the Performer shall make the physician statements, and informed consents required by 42 USC 289g-1(b) and (c) available for audit by the HHS Secretary, or shall ensure HHS access to those records if they are maintained by an entity other than the Performer.

D. Human Embryo Research and Cloning

HHS funds may not be used to support human embryo research. In addition, no funding may be used for cloning human beings.

E. Needle Exchange

The Performer shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ANIMAL SUBJECT RESEARCH (ASR)

A. Care of Live Vertebrate Animals

1. Before undertaking performance of any research involving animal related activities, the Performer shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.27. The Performer shall furnish evidence of the registration to the AO.

2. The Performer shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.13, or from a source that is exempt from licensing under those sections.

3. The Performer agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this Agreement will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the National Academy of Sciences Institute of Laboratory Animal Resources, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1- 4). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this Agreement, and in consultation with the Office of Laboratory Animal Welfare (OLAW) of the National Institutes of Health (NIH), the AO determines that the Performer is not in compliance with any of the requirements and/or standards stated in paragraphs 1 through 3 of this Article, the AO may immediately suspend, in whole or in part, work and further payments under this Agreement until the Performer corrects the non-compliance. Notice of the suspension may be communicated by telephone but will be confirmed in writing. If the Performer fails to complete corrective action within the period designated in the AO's written notice of suspension, the AO may, in consultation with OLAW, terminate this Agreement in whole or in part, and the Performer's name may be removed from the list of those organizations with approved PHS Animal Welfare Assurances.

> **Note**: The Performer may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

B. Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*, the *Animal Welfare Act* (7 U.S.C. 2131 et. seq.), the *U.S. Government Principles and the Guide for the Care and Use of Laboratory Animals*.

C. Protection of Personnel Who Work with Nonhuman Primates

All Performer personnel who work with non-human primates, or who enter rooms or areas containing non-human primates, shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "*Protection of NIH Personnel Who Work with Non-Human Primates*."

D. Information on Compliance with Animal Care Requirements

1. Registration with the U.S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. The USDA is responsible for the enforcement of the *Animal Welfare Act* (7 U.S.C. 2131 et. seq.). The Public Health Service (PHS) policy is administered by the OLAW. An essential requirement of the PHS policy is that every institution using live vertebrate animals must obtain an approved assurance from the OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Performer does not have an assurance and will be using a subaward to perform the animal work, the Performer and subawardee must have an Inter-Institutional Assurance in place to allow the Performer to use the assurance of the subawardee to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to the OLAW by NIH on behalf of the Performer.

2. The PHS policy requires that Assured Institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the *Animal Welfare Act*. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy. The *Association for Assessment and Accreditation of Laboratory Animal Care International* (AAALAC) is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. The AAALAC uses the Guide as its primary evaluation tool. It also uses the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching,* published by the Federation of Animal Science Societies.

E. Approval of Required Assurance by Law

Federal funds shall not be expended by the Performer for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Performer under this award unless a satisfactory assurance of compliance with

- the *Animal Welfare Act*, including 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28,
- the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*, and
- the *U.S. Government Principles and the Guide for the Care and Use of Laboratory Animals*

is submitted by Performer 30 days prior to commencing research involving live vertebrate animals and approved by the OLAW. Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction:

> *Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective Assurance(s) of Compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28.*

SALARY RATE LIMITATION

1. The Performer shall not use program funds (under this Agreement) to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated. For the purposes of the salary rate limitation, "direct salary," "salary", and "institutional base salary" have the same meaning as and are collectively referred to as "direct salary." An individual's direct salary is the annual compensation that the Performer pays (direct labor costs) for an individual's direct effort under the Agreement. Direct salary excludes any income that an individual may be permitted to earn outside of their duties to the Performer. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

   NOTE: The salary rate limitation does not restrict the salary that an organization may pay an individual working under the Agreement; it merely limits the portion of that salary that may be paid with federal funds.

2. The salary rate limitation also applies to individuals under subawards.

REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste, or abuse under federal awards. Information also may be submitted online at https://tips.oig.hhs.gov/ or by mail to U.S. Department of Health and Human Services, Office of the Inspector General, Attn: OIG HOTLINE OPERATIONS, P.O. Box 23489 Washington DC 20026. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous. For additional information, see: https://oig.hhs.gov/fraud/report-fraud/.

PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Performer acknowledges that U.S. Executive Orders and laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to individuals and organizations associated with terrorism. It is the legal responsibility of the Performer to ensure compliance with these Executive Orders and laws. The Performer shall include this paragraph, suitably modified, in all subcontracts or lower tier agreements.

RESEARCH MISCONDUCT

Title 42 CFR 93, *PHS Policies on Research Misconduct*, Subpart C, *Responsibilities of Institutions*, specifies awardee responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity (ORI) and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The ORI has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct, and facilitates the responsible conduct of research through education, and preventive and regulatory activities.

REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

1. Work involving select biological agents or toxins shall not be conducted under this Agreement until the Performer and any affected subawards are granted a certificate of registration or are authorized to work with the applicable Select Agents.

2. For prime or subawards to domestic institutions who possess, use, and/or transfer Select Agents under this Agreement, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No federal funds can be used for work involving Select Agents as defined in 42 CFR 73 if the final registration certificate is denied.

3. For prime- or subawards to foreign institutions who possess, use, and/or transfer Select Agents under this Agreement, the foreign institutions must provide information satisfactory to the government that a process equivalent to that described in 42 CFR 73 is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Performer must provide information addressing the following key elements appropriate for the foreign institution(s):

    - safety,
    - security,
    - training,
    - procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and
    - any applicable laws, regulations and policies equivalent to 42 CFR 73.

4. The government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the AO, the Performer shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For security risk assessments, the Performer must provide the names of all individuals at the foreign institution who will have access to the Select Agents and must identify its procedures for ensuring that only approved and appropriate individuals have access to Select Agents under this Agreement.

5. Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES

The Performer shall ensure that all work involving the use of recombinant DNA will comply with the "*National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules*."

DARÉ BIOSCIENCE, INC.

AMENDED AND RESTATED INSIDER TRADING POLICY
(effective October 22, 2024)

TABLE OF CONTENTS

This Insider Trading Policy (this "Insider Trading Policy" or "Policy") is designed to prevent insider trading or the appearance of impropriety, to satisfy the obligation of Daré Bioscience, Inc. ("Company"), to reasonably supervise the activities of Company personnel, and to help Company personnel avoid the consequences associated with violations of insider trading laws.

This Policy applies to *all* Company personnel, including directors, officers, employees and consultants of the Company and its subsidiaries. This Policy also applies to certain family members, other members of a person's household and entities controlled by Company personnel, as described in Section IV below.

I. The Need for an Insider Trading Policy

This Policy has been developed:

- to educate all Company personnel as to the federal securities laws and the rules of the Securities and Exchange Commission (the "SEC") on insider trading in public company securities;
- to set forth requirements that apply to Company personnel and other persons covered by this Policy who seek to trade in the Company's securities;
- to protect the Company and its personnel from legal liability; and
- to preserve the reputation of the Company and its personnel for integrity and ethical conduct.

Because the Company is a public company, transactions in the Company's securities are subject to the federal securities laws and regulations adopted by the SEC. These laws and regulations make it illegal for an individual to buy or sell securities of the Company while aware of ***material non-public information***. The SEC takes insider trading very seriously and devotes significant resources to uncovering the activity and to prosecuting offenders. Liability may extend not only to the individuals who trade while in possession of material non-public information but also to their "tippers," people who leak material non-public information to individuals who then trade based on that information. The Company and "controlling persons" of the Company may also be liable for violations by Company employees.

II. What is Material Non-Public Information?

Definition.

Material non-public information is any information (positive or negative) that:

- is not generally known to the public, and
- which, if publicly known, would likely affect either the market price of the Company's securities or a person's decision to buy, sell or hold the Company's securities.

Examples. Common examples of information that will frequently be regarded as material include, but are not limited to:

- quarterly or annual earnings results;
- projections of future financial results;
- earnings or losses;
- news of a pending or proposed merger, acquisition or tender offer;

- news of a pending or proposed acquisition or disposition of a significant asset;
- news of a pending or proposed joint venture;
- a company restructuring;
- significant transactions with officers, directors or greater than 5% stockholders;
- financing transactions;
- changes in dividend policies, the declaration of a stock split or the offering of additional securities;
- establishment of a stock repurchase program;
- changes in pricing or cost structure of Company products or services;
- changes in management;
- changes in auditors or notification that the auditor's reports may no longer be relied upon;
- significant new products or discoveries;
- significant clinical or regulatory developments;
- pending or threatened significant litigation, or the resolution of such litigation;
- impending bankruptcy or financial liquidity problems;
- internal financial information which departs from what the market expects;
- the gain or loss of a significant customer or supplier, major contract, license, registration or collaboration;
- the entry, amendment or termination of a material contract; or
- other items that require the filing of a Current Report on Form 8-K with the SEC.

Twenty-Twenty Hindsight. In determining whether information is material, the SEC and other regulators will view the information after-the-fact with the benefit of hindsight. As a result, in determining whether any information is material, we will and you should carefully consider whether regulators and others might view the information as being material in hindsight, with the benefit of all relevant information that later becomes available. For example, if there is a significant change in the Company's stock price following release of certain information, that information will likely be determined to have been material when viewed with the benefit of hindsight.

In addition to addressing the relevant statutes and regulations in this area, we are adopting this Policy to avoid even the appearance of improper conduct on the part of anyone employed by or associated with the Company and certain related persons, not just members of senior management.

III. The Consequences of Insider Trading

The consequences of insider trading violations can be severe:

For individuals who trade while in possession of material non-public information (or tip information to others):

- a civil penalty of up to three times the profit gained or loss avoided;
- a criminal fine (no matter how small the profit) of up to $5 million; and

- a jail term of up to 20 years.

These penalties can apply even if the individual is not a member of the Board of Directors or an officer of the Company. Moreover, if an employee violates this Policy, he or she may also be subject to Company-imposed sanctions, including termination for cause.

For a company (as well as possibly any supervisory person) that fails to take appropriate steps to prevent illegal trading:

- a civil penalty of the greater of $1 million or three times the profit gained or loss avoided as a result of the employee's violation; and
- a criminal penalty of up to $25 million.

Any of the above consequences, including an SEC investigation that does not result in prosecution, can tarnish the Company's or an individual's reputation and irreparably damage a career.

IV. Our Policy

General Prohibition on Trading in Company Securities. Company personnel and Related Persons (as defined below in this Section IV) may not engage in transactions in securities of the Company, directly or indirectly, while in possession of material non-public information relating to the Company, subject to the specific exceptions noted below in this Section IV under the caption "Exceptions for Certain Transactions."

General Prohibition on Tipping. Company personnel in possession of material non-public information relating to the Company may not recommend that others engage in transactions in securities of the Company, disclose material non-public information relating to the Company to others, except as permitted under applicable Company policies and procedures, or assist anyone engaged in such activities.

Transactions by Family Members, Others in Your Household and Entities You Control. The restrictions in this Policy also apply to (1) family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), (2) others living in your household (whether or not related to you), (3) family members who do not live in your household but whose transactions in the Company's securities are directed by you or are subject to your influence or control (e.g., parents or children who consult with you before they trade in the Company's securities) and (4) any entities that you influence or control, including any corporations, limited liability companies, partnerships or trusts (each person or entity identified in clauses (1) – (4), a "Related Person"). SEC regulations specifically provide that any material non-public information about the Company communicated to any spouse, parent, child or sibling is considered to have been communicated under a duty of trust or confidence; and that any trading in the Company's securities by such family members while they are aware of such information may, therefore, violate insider trading laws and regulations. Company personnel are expected to be responsible for the compliance of all Related Persons with this Policy. This means that, to the extent such Related Persons of Company personnel intend to engage in any transaction in securities of the Company, the Related Persons need to comply with the black-out periods and all other restrictions in this Policy. Furthermore, you should not participate in any investment club (i.e., groups of people who pool their money to make investments) that may invest in the Company's securities.

Other Companies' Securities. This Policy's prohibitions against trading and tipping also apply to securities of other public companies as described herein. In the course of your service to or employment with the Company, you may learn of material non-public information about other public companies, including the Company's collaborators, customers, distributors, suppliers or other vendors, and companies involved in a potential transaction or business relationship with the Company. Therefore, no Company personnel who, in the course of their service to or employment with the Company, learns of material non-public information about the Company or a company with which the Company does business or is involved in a potential transaction or business relationship with the Company, may engage in transactions, directly or indirectly, in (1) the securities of such company if that company has publicly-traded securities, or (2) the securities of any other publicly-traded company where the applicable material non-public information relates to that other publicly-traded company, in each case until such information becomes public or is no longer material. Further, Company personnel in possession of such material non-public information may not recommend that others engage in any of the foregoing transactions, disclose such material non-public information to others, except as permitted under applicable Company policies and procedures, or assist anyone engaged in such activities.

Personal or Independent Reasons Are Not Exceptions. Transactions in the Company's securities that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) are no exception. Even the appearance of an improper transaction must be avoided to preserve our reputation for adhering to the highest standards of conduct.

Policy Administrator. This Policy shall be administered by the "Policy Administrator," who shall be the Company's principal financial officer ("PFO"). If the PFO is not available or a matter under this Policy involves the PFO, then the Company's principal accounting officer ("PAO") shall serve as the alternate Policy Administrator. If the PAO is serving as the Policy Administrator and is not available or a matter under this Policy involves the PAO, then another person designated by the Nominating and Corporate Governance Committee of the Board shall serve as the alternate Policy Administrator.

When Information Becomes Public. Because the Company's stockholders and the investing public should be afforded time to receive and absorb material non-public information, for purposes of this Policy, as a general rule, you may not engage in any transactions prohibited by this Policy until after two full Trading Sessions (as defined below) following the widespread public release of the applicable information. Thus, for example, if material non-public information is publicly disseminated *before* 9:30 a.m. Eastern Time on a Monday, you may not engage in any transactions prohibited by this Policy until after the Trading Session ends on Tuesday, assuming Trading Sessions took place on Monday and Tuesday. Likewise, if material non-public information is publicly disseminated *before* 9:30 a.m. Eastern Time on a Friday, you may not engage in any transactions prohibited by this Policy until after the Trading Session ends on Monday, assuming Trading Sessions took place on Friday and Monday. For another example, if material non-public information is publicly disseminated *after* 9:30 a.m. on a Monday, you may not engage in any transactions prohibited by this Policy until after the Trading Session ends on Wednesday, assuming Trading Sessions took place on Tuesday and Wednesday. However, if the applicable information is complex, such as a significant corporate transaction or significant clinical or regulatory development, it may be necessary to allow additional time for the information to be absorbed by the Company's stockholders and investing public. In such circumstances, you will

be notified by the Policy Administrator regarding a suitable additional waiting period before you may engage in any transactions prohibited by this Policy. In addition, we have established specified black-out periods, as described below.

For purposes of this Policy, a "Trading Session" means a regular trading session of the United States national securities exchange on which the Company's common stock is primarily listed, typically 9:30 a.m. Eastern Time to 4:00 p.m. Eastern Time on business days. For the avoidance of doubt, a Trading Session includes a pre-scheduled abbreviated trading session, such as 9:30 a.m. Eastern Time to 1:00 p.m. Eastern Time on November 29, 2024 and December 24, 2024.

Prohibited Trading Periods. While it is never permissible to trade based on material non-public information, we are implementing the following procedures to help prevent inadvertent violations of this Policy and avoid even the appearance of an improper transaction (which could result, for example, where Company personnel engage in a trade while unaware *of a pending major development).*

(1) Company Wide Black-Out Periods Applicable to All Company Personnel. All Company personnel and Related Persons are prohibited from trading in any of the Company's securities during the following periods:

- from the time each such individual becomes aware of the material non-public information (the black-out start times often vary), until after two full Trading Sessions following the widespread public announcement of the applicable information, unless the information released is complex, in which case it may be necessary to extend this period and the Policy Administrator will notify you of any such extension; and
- during other specified periods when significant developments or announcements are anticipated, as notified by the Policy Administrator.

You will be notified by e-mail when you may not trade in the Company's securities during periods when significant developments or announcements are anticipated, in which event you will also be notified when trading restrictions are lifted. *Of course, even during periods when trading is permitted, no one, including persons or entities who do not fall within the definition of Related Persons, should trade in the Company's securities if he or she possesses material non-public information.*

(2) Additional Black-Out Periods Applicable to the Board of Directors, Senior Management, Financial Team Members and Designated Employees. In addition to being subject to the trading restrictions applicable to all Company personnel (above), members of the Company's Board of Directors, Senior Management, Financial Team Members, Designated Employees (each as defined below) and Related Persons of such individuals are also subject to additional trading procedures and restrictions during the following periods:

- the periods from two weeks prior to the close of each fiscal quarter until after two full Trading Sessions following the widespread public release of the Company's financial results for the applicable quarter and, in the case of the fourth quarter, financial results for the year ended; and
- any other periods as determined by the Policy Administrator.

The following members of management constitute the "Senior Management" of the Company: all Executive (Section 16) Officers, as listed on Exhibit A hereto, which list shall be amended from time to time to reflect the then-current group of such individuals.

The following individuals constitute the "Financial Team Members" of the Company: all members of the Company's financial team, as listed on Exhibit B hereto, which list shall be amended from time to time to reflect the then-current group of such individuals.

The following individuals constitute other "Designated Employees" of the Company: certain additional members of Company personnel, as listed on Exhibit C hereto, which list shall be amended from time to time to reflect the then-current group of such individuals.

The Policy Administrator may, from time to time, amend the list of and/or designate other employees as Senior Management, Financial Team Members or Designated Employees, in which case the Policy Administrator shall notify the affected individuals.

Exceptions for Certain Transactions.

(1) Gifts. *Bona fide* gifts of securities to other Company personnel or Related Persons are not transactions that are subject to this Policy. This Policy does apply, however, to subsequent transactions in the gifted securities by such recipients. In addition, this Policy does apply to gifts of securities, including *bona fide* gifts, to persons who are not Company personnel or Related Persons.

(2) Mutual Funds. Transactions in mutual funds that are invested in the Company's securities are not transactions subject to this Policy.

(3) Transactions Involving Company Equity Plans. Except as otherwise noted below, this Policy does not apply to the following transactions:

- *Stock Option Exercises.* This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's equity plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale of stock for the purpose of generating the cash needed to pay the exercise price and or taxes upon the exercise of an option.
- *Restricted Stock Awards and Restricted Stock Unit Awards.* This Policy does not apply to the vesting of restricted stock or restricted stock units, or the exercise of a tax withholding right pursuant to which a person elects to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock or restricted stock unit. This Policy does apply, however, to any market sale of restricted stock or shares received upon vesting of restricted stock units.
- *Employee Stock Purchase Plan.* This Policy does not apply to purchases of the Company's securities under the Company's employee stock purchase plan. This Policy does apply, however, to subsequent sales or other transfers of such securities.
- *Other Transactions with the Company.* Any other purchase of the Company's securities from the Company or sales of the Company's securities to the Company are not subject to this Policy.

(4) Rule 10b5-1 Trading Plans. Notwithstanding the restrictions and prohibitions on trading in the Company's securities set forth in this Policy, persons subject to this Policy are permitted to effect transactions in the Company's securities pursuant to approved trading arrangements intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)(1), or any successor rule(s), under the Securities Exchange Act of 1934, as amended ("Trading Plans"), which may include transactions during the prohibited periods discussed above. A Trading Plan may be established only when the person who enters into the Trading Plan is not aware of any material non-public information about the security or the issuer and is adopting the Trading Plan in good faith and not as a part of a plan or scheme to evade the prohibitions of Rule 10b-5. In order to comply with this Policy, the Company must pre-approve any such Trading Plan prior to its effectiveness. All Trading Plans must designate a "cooling-off period" after the Trading Plan is adopted and before the first trade is made under the Trading Plan, the length of which will be determined by the Policy Administrator and must, at minimum, satisfy the applicable cooling-off period required by Rule 10b5-1(c)(1)(ii)(B), or any successor rule(s). Once the Trading Plan is adopted, you must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the timing of the trades. The Trading Plan must specify the amount, pricing and date of transactions, or include a written formula or algorithm, or computer program, for determining the amount, pricing and date of transactions, or delegate discretion on these matters to an independent third party. Any modification or change to the amount, price, or timing of the purchase or sale of securities under a Trading Plan is the equivalent of termination of such Trading Plan and the adoption of a new Trading Plan. A plan modification, such as the substitution or removal of a broker that is executing trades pursuant to a Trading Plan that changes the price or date on which purchases or sales are to be executed, is the equivalent of termination of such Trading Plan and the adoption of a new Trading Plan. Company personnel seeking to establish, modify or cancel a Trading Plan should contact the Policy Administrator.

Pre-Clearance of All Acquisitions, Sales and Other Transfers by Certain Company Personnel. In order to ensure compliance with this Policy and with any Section 16 reporting requirements, all transactions in the Company's securities (including acquisitions, sales, gifts and other transfers, whether or not for value), including the execution of Trading Plans (as defined below), by members of the Company's Board of Directors, Senior Management, Financial Team Members, Designated Employees and Related Persons, must be pre-cleared by the Policy Administrator. If you are a member of one of the groups listed above and you contemplate a transaction in the Company's securities, you must contact the Policy Administrator or other designated individual prior to executing the transaction. The Policy Administrator will use their reasonable best efforts to provide approval or disapproval within two business days. You must wait until receiving pre-clearance to execute the transaction. Neither the Company nor the Policy Administrator shall be liable for any delays that may occur due to the pre-clearance process. If the transaction is pre-cleared by the Policy Administrator, it must be executed by the end of the second business day after receipt of pre-clearance. Notwithstanding receipt of pre-clearance of a transaction, if you become aware of material non-public information about the Company after receiving the pre-clearance but prior to the execution of the transaction, you may not execute the transaction. The responsibility for determining whether you are in possession of material non-public information rests with you, as discussed below in Section V. If you are a Section 16 reporting person, promptly following execution of any transaction in the Company's securities (including any disposition of securities of the Company by bona fide gifts), but in no event later than the end of the first business day after the execution of the transaction, you must notify the

Policy Administrator and provide details regarding the transaction sufficient to complete the required Section 16 filing.

Employees of the Company who are not Directors, members of Senior Management, Financial Team Members or Designated Employees may, but are not required to, pre-clear transactions in the Company's securities in the same manner as set forth above. Such employees are not required to notify the Policy Administrator following execution of the transaction.

Please note that pre-clearance does not provide Company personnel with immunity from investigation or suit, for which it is the responsibility of the individual to comply with the federal securities regulations.

V. Individual Responsibility

Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in the Company's securities while in possession of material non-public information. Each individual is responsible for making sure that he or she complies with this Policy, and that any Related Person, whose transactions are subject to this Policy, also comply with this Policy. In all cases, the responsibility for determining whether an individual is in possession of material non-public information rests with that individual, and any action on the part of the Company, the Policy Administrator or any other employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You may be subject to legal penalties and disciplinary action by law enforcement officials and/or the Company for any conduct prohibited by this Policy or applicable securities laws, as described in Section III above.

Tipping Information to Others. Company personnel must not disclose non-public information about the Company to others outside the Company who do not have an obligation to maintain the confidentiality of such information. If the outsider trades on such information, penalties for insider trading may apply in these situations whether or not you derive any monetary benefit from the other person's trading activities. Material non-public information is often inadvertently disclosed or overheard in casual, social conversations. Please take care to avoid such disclosures.

Prevention of Insider Trading by Others. If you become aware of a potential insider trading violation, you must immediately advise our Policy Administrator and/or report the matter using the Company's anonymous whistleblower reporting procedures. You should also take steps, where appropriate, to prevent persons under your supervision and/or control from using material non-public information for trading purposes. Moreover, Company-imposed sanctions, including termination for cause, could result if an employee fails to comply with this Policy.

Confidentiality. Serious problems could be caused for the Company by the unauthorized disclosure of internal information about the Company, whether or not for the purpose of facilitating improper trading in the Company's securities. Company personnel should not discuss internal Company matters or developments (whether or not you think such information is material) with anyone outside of the Company (including, but not limited to, family, friends, business associates, investors and expert consulting firms), except as required in the performance of regular corporate duties. This prohibition applies specifically (but not exclusively) to inquiries about the Company that may be made by the financial press, investment analysts or others in the financial community

and also includes posting material non-public information on any social media outlets such as LinkedIn, Facebook, X (formerly Twitter), etc. It is important that all such communications on behalf of the Company be made only through an authorized officer under carefully controlled circumstances. Unless you are expressly authorized to the contrary, if you receive any inquiries of this nature, you should decline comment and refer the inquirer to the Policy Administrator.

VI. Additional Prohibited Transactions

Because we believe it is generally improper and inappropriate for Company personnel to engage in short-term or speculative transactions involving the Company's securities, it is our policy that Company personnel and Related Persons not engage in any of the following activities, except in each case in limited circumstances with prior approval of the Policy Administrator:

- trading in the Company's securities on a short-term basis (any shares of Company common stock purchased in the open market must be held for a minimum of six months and ideally longer);
- short sales of the Company's securities;
- use of the Company's securities to secure a margin or other loan; and
- transactions in publicly-traded options relating to the Company's securities (i.e., options that are not granted by the Company).

In addition, Company personnel and Related Persons (or any of their designees) are prohibited from purchasing financial instruments (including prepaid variable forward contracts, equity swaps, collars, and exchange funds), or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value of the Company's equity securities.

VII. Post-Termination Transactions

This Policy will no longer apply after termination of service to the Company. However, if an individual is in possession of material non-public information when his or her service terminates, that individual may not trade in the Company's securities until that information has become public or is no longer material, and it would be prudent for the individual, if he or she is subject to a black-out period upon termination of service, to refrain from trading until those restrictions no longer apply to Company personnel.

VIII. Company Assistance

Any person who has any questions about specific transactions or this Policy in general may obtain additional guidance from the Policy Administrator. Remember, however, the ultimate responsibility for adhering to this Policy and avoiding improper transactions rests with you. In this regard, please use your best judgment when considering a transaction in the Company's securities.

IX. Certifications

As a condition to employment, all employees will be required to certify their understanding of and intent to comply with this Policy. Members of the Board of Directors, Senior Management and other personnel (including employees) may be required to periodically certify their compliance with this Policy and their understanding of and intent to continue to comply with this Policy.

As of December 6, 2024:

Exhibit A

"Senior Management"

All Executive (Section 16) Officers, including:

1. Sabrina Martucci Johnson, President and Chief Executive Officer
2. MarDee Haring-Layton, Chief Accounting Officer

Exhibit B

"Financial Team Members"

All members of the Company's financial team, including:

1. Sabrina Martucci Johnson, President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)
2. MarDee Haring-Layton, Chief Accounting Officer (Principal Accounting Officer)
3. Natasha Zhigalko, Controller
4. Stephanie Li Fraine, Sr. Accountant

Exhibit C

"Designated Employees"

All Company employees are currently considered to be Designated Employees, and as such, are subject to the Company's Additional Black-Out Periods and restrictions. The Company may change the definition of Designated Employees at any time.

Certification Under Insider Trading Policy

The undersigned hereby certifies that he/she has read and understands, and agrees to comply with the Daré Bioscience, Inc. Amended and Restated Insider Trading Policy, a copy of which was distributed with this Certification, as a condition to the undersigned's present and continued employment or other affiliation with the Company.

Date: _____

Name: _____

Title: _____

CONSULTANTS NEED NOT SIGN THIS PAGE. INSTEAD, CONSULTANTS ARE TO EXECUTE AND RETURN THE SIGNATURE PAGE OF THE CONSULTANT ADDENDUM TO LMURPHY@DAREBIOSCIENCE.COM.

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	**Jurisdiction of Organization**
Daré Bioscience Operations, Inc.	Delaware
Daré Bioscience Australia Pty Ltd	Australia
Pear Tree Pharmaceuticals, Inc.	Delaware
Daré MBI Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-283280), the Registration Statements on Form S-3 (File Nos. 333-278380, 333-278378, 333-254862 and 333-238299) and the Registration Statements on Form S-8 (File Nos. 333-264020, 333-266699, 333-254864, 333-237473, 333-230802, 333-226904, 333-211697, 333-204007, and 333-198126) of Daré Bioscience, Inc. (the "Company") of our report dated March 31, 2025, relating to the consolidated financial statements as of December 31, 2024 and 2023 and for each of the years in the two-year period then ended (which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern), which appear in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

/s/ Haskell & White, LLP
HASKELL & WHITE LLP

Irvine, California
March 31, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Sabrina Martucci Johnson, certify that:

1. I have reviewed this annual report on Form 10-K of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2025

/s/ Sabrina Martucci Johnson
Sabrina Martucci Johnson
President and Chief Executive Officer
(Principal executive officer and principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Daré Bioscience, Inc. (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2025

/s/ Sabrina Martucci Johnson
Sabrina Martucci Johnson
President and Chief Executive Officer
(principal executive officer and principal financial officer)