darébio

ANNUAL REPORT 2020

We're driven by a mission to accelerate a diverse portfolio of novel therapies for women that expand treatment options, improve outcomes and facilitate convenience.

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, 2020
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 under 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 under 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 Exchange 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. ☐

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 (June 30, 2020), was approximately $22,800,000 based on the closing price of the registrant's common stock as reported on the Nasdaq Capital Market on such date. 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 29, 2021, there were 47,312,822 shares of the registrant’s common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Daré Bioscience, Inc. and Subsidiaries

Form 10-K – ANNUAL REPORT

For the Fiscal Year Ended December 31, 2020

Table of Contents

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 costs, 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," "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 continue as a going concern;*
- *Inability to raise additional capital, under favorable terms or at all, including as a result of the effects of the COVID-19 pandemic;*
- *Inability to successfully attract partners and enter into collaborations relating to the development and/or commercialization of our product candidates on a timely basis or on acceptable terms, or at all;*
- *A decision by Bayer HealthCare LLC to discontinue its commercial interest in Ovaprene® and/or to terminate our license agreement;*
- *Inability or an increase in projected costs to timely develop, obtain regulatory approval for and commercialize our product candidates;*
- *Failure or delay in starting, conducting and completing clinical trials or obtaining United States Food and Drug Administration, or FDA, or foreign regulatory approval for our product candidates in a timely manner, including as a result of matters beyond our control such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic;*
- *A change in the FDA Center assigned primary oversight responsibility for our combination product candidates;*
- *A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FDA's 505(b)(2) pathway;*
- *Unsuccessful clinical trial outcomes stemming from clinical trial designs, failure to enroll a sufficient number of patients, higher than anticipated patient dropout rates, failure to meet established clinical endpoints, undesirable side effects and other safety concerns;*
- *Reaching a conclusion regarding the efficacy or safety of a product candidate following full evaluation of complete clinical study data that is materially different from topline study results we may report;*
- *Communication from the FDA or another regulatory authority that it 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 it 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;*
- *Negative publicity concerning the safety and efficacy of our product candidates, or of product candidates being developed by others that share characteristics similar to our candidates;*
- *Inability to demonstrate sufficient efficacy of our product candidates;*
- *Failure to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates due to limited financial resources;*
- *Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;*

- *Monetary obligations and other requirements in connection with our exclusive, in-license agreements covering the patents and related intellectual property related to our product candidates, or our merger or asset purchase agreements relating to the acquisition of our product candidates;*
- *Developments by our competitors that make our product candidates less competitive or obsolete;*
- *Dependence on third parties to conduct nonclinical studies and clinical trials of our product candidates;*
- *Dependence on third parties to supply and manufacture clinical trial materials and, if any of our candidates are approved, commercial product, including components of our products as well as the finished product, in accordance with current good manufacturing practices and in the quantities needed;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems or the technology systems of third parties on which we rely;*
- *Interruptions in, or the complete shutdown of, the operations of third parties on which we rely, including clinical sites, manufacturers, suppliers, and other vendors, from matters beyond their control, such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic, and our lack of recourse against such third parties if their inability to perform is excused under the terms of our agreements with such parties;*
- *Failure of our product candidates, if approved, to gain market acceptance or obtain adequate coverage for third party reimbursement;*
- *A reduction in demand for contraceptives caused by an elimination of current requirements that health insurance plans cover and reimburse certain FDA-cleared or approved contraceptive products without cost sharing;*
- *Uncertainty as to whether health insurance plans will cover our product candidates even if we successfully develop and obtain regulatory approval for them;*
- *Unfavorable or inadequate reimbursement rates for our product candidates set by the United States government and other third-party payers even if they become covered products under health insurance plans;*
- *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 certain of our product candidates which could expose those product candidates to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in pre-clinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could subject us to securities class-action litigation;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *Litigation or public concern about the safety of our potential products;*
- *Strict government regulations on our business, including 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;*
- *Regulations governing the production or marketing of our product candidates;*
- *Loss of, or inability to attract, key personnel; 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 clinical-stage biopharmaceutical company committed to advancing innovative products for women’s health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility.

Our Strategy

Our business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid to late-stage clinical development, and to establish and leverage strategic partnerships to achieve commercialization.

We believe that there is an opportunity to fill the gap that exists in the development of innovations in women’s health between (a) non-profit organizations, small private companies and individual entrepreneurs that discover, innovate and conduct early-stage research and clinical development of product candidates, and (b) pharmaceutical companies that conduct late-stage clinical development and commercialize approved products. We believe that the development activities between these two ends of this spectrum (early pre-clinical and clinical development of product candidates on the one hand and late-stage clinical trials and commercialization of product candidates on the other) are currently underserved. In addition, we believe there are gaps in treatment options in the women's health market and there is an opportunity to provide therapies that address persistent unmet needs. We intend to fill the mid-stage development gap and to address the gaps in treatment options for women.

The dynamics of the women’s health market provide an opportunity for us to assemble a portfolio of product candidates, including clinical-stage candidates, often with published human data. Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through mid and late stages of clinical development or FDA approval.

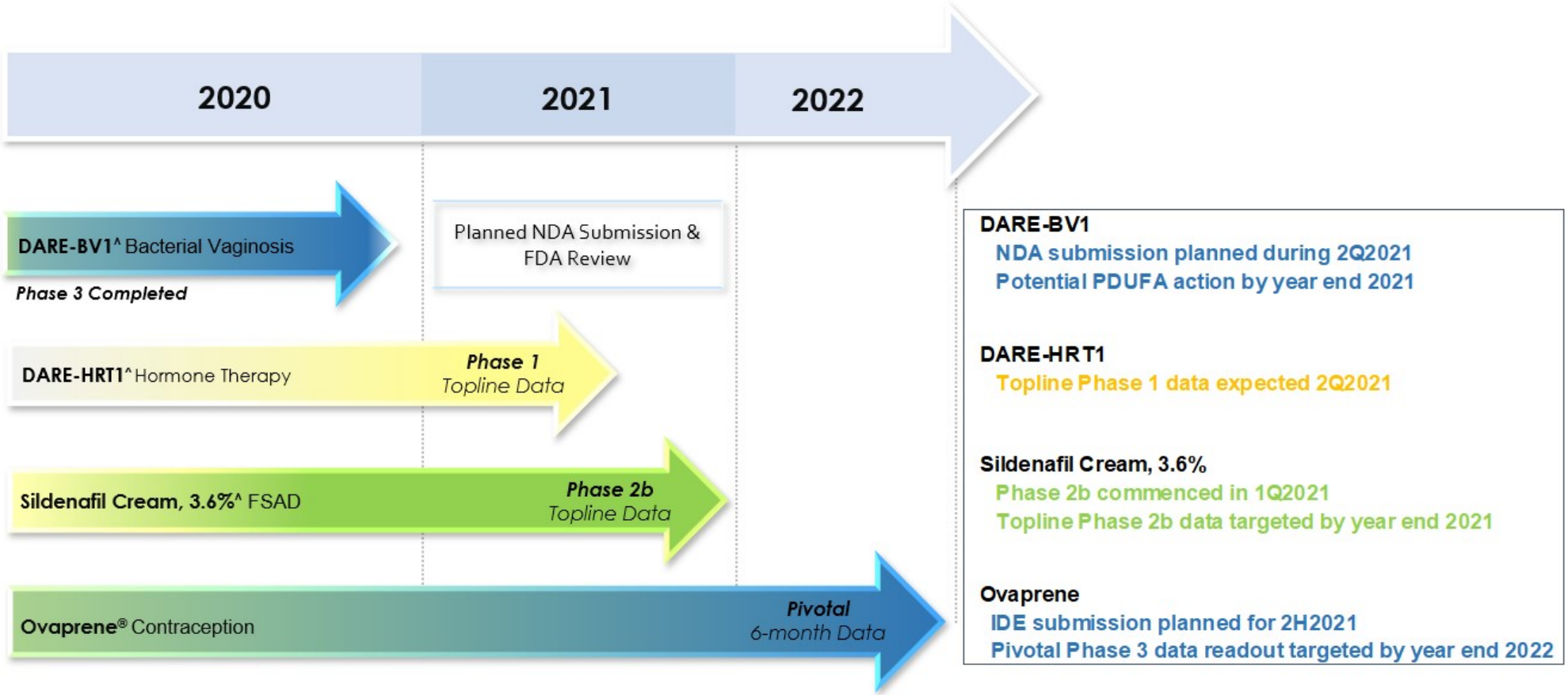
Our Clinical-Stage and Phase 1-ready Product Candidates and Programs

Our development strategy is two-fold:

(1) We intend to use existing data and any data we generate to prepare Investigational New Drug applications, or INDs, or Investigational Device Exemption applications, or IDEs, to the extent these have not already been prepared, and to design and implement additional pre-clinical and clinical trials to advance our programs toward the submission of New Drug Applications, or NDAs, or Premarket Approvals, or PMAs, for regulatory approval of our product candidates in the U.S.

(2) We intend to identify FDA-approved drugs and therapies that might benefit from a different formulation, manner of application or delivery method to enhance therapeutic outcomes and to expedite the development of these candidates under the FDA's 505(b)(2) pathway.

Our initial focus is in the areas of contraception, vaginal health, sexual health and fertility, and we have acquired, or acquired rights to, candidates in these areas with promising early clinical and/or pre-clinical testing data developed by third parties. We believe the product candidates currently in our portfolio offer innovative therapeutic approaches that may provide meaningful benefits over current treatment options. Our portfolio includes three product candidates in advanced stages of clinical development and three product candidates in Phase 1 clinical development or that we believe are Phase 1-ready. The following graphic provides a snapshot of our clinical-stage product candidates, including their targeted indications and our current expectations for their respective stages of development in 2021:



DARE-BV1 NDA filing and **two** top-line data readouts expected during **2021**

^ We intend to utilize the FDA's 505(b)(2) pathway for this product candidate.

DARE-BV1

DARE-BV1 is a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% that we are developing as a first-line, single-administration treatment for bacterial vaginosis. Clindamycin is an antibiotic with FDA approval to treat certain bacterial infections, including in cream formulations to treat bacterial vaginosis. DARE-BV1 is designed to transition from a viscous liquid to a bioadhesive gel at body temperature following vaginal self-administration. The bioadhesive properties and release profile of DARE-BV1 are expected to reduce leakage and prolong the duration of exposure to the active drug relative to currently marketed creams and gels with FDA-approval to treat bacterial vaginosis, potentially improving the rate of clinical effectiveness compared to those existing therapies. We plan to leverage existing safety and efficacy data on clindamycin to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-BV1 for bacterial vaginosis in the U.S. We are not aware of any unexpired patent or non-patent market exclusivities for clindamycin, and we do not expect to make any Paragraph IV certification in the NDA for DARE-BV1. The FDA's 505(b)(2) pathway and Paragraph IV certifications are described in more detail below under "Government Regulation – U.S. Government Regulation – FDA Approval Process for Prescription Drugs – Marketing Application Submission and FDA Review," and "Government Regulation – U.S. Government Regulation – New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension – Orange Book Listing & Patent Certification" and "– Non-Patent Exclusivities."

According to the Centers for Disease Control and Prevention, or the CDC, bacterial vaginosis is the most common vaginal condition in women ages 15-44. Bacterial vaginosis is a type of vaginal inflammation caused by the overgrowth of certain bacteria naturally found in the vagina. Symptoms include vaginal discharge, vaginal odor, vaginal pain, itching or burning, and burning during urination. We believe current bacterial vaginosis therapies are inadequate and there is a significant unmet need for better treatment. Current FDA-approved therapies have clinical cure rates (based on the Amsel criteria) ranging from 37-68%.

In August 2019, the FDA granted DARE-BV1 Qualified Infectious Disease Product (QIDP) designation for the treatment of bacterial vaginosis in women. Because of its QIDP designation, if DARE-BV1 is approved by the FDA for the treatment of bacterial vaginosis in women, we expect it to receive the five-year GAIN Act exclusivity extension to any non-patent marketing exclusivity period for which it qualifies upon approval. In March 2020, we announced that we received Fast Track designation from the FDA for DARE-BV1 for the treatment of bacterial vaginosis. The designation offers the opportunity for more frequent interactions with the FDA to discuss DARE-BV1's development plan and ensure collection of appropriate data needed. The Fast Track program is intended to facilitate development and expedite review of a Fast Track drug so that an approved product can reach the market expeditiously. Given DARE-BV1's QIDP and Fast Track designations, its NDA for bacterial vaginosis could be eligible for priority review by the FDA, and we intend to request priority review upon submission of the NDA as further discussed below. For additional information about the FDA's QIPD, Fast Track and priority review programs, please see the discussion below under "Government Regulation – U.S. Government Regulation – FDA Approval Process for Prescription Drugs – Special FDA Programs to Facilitate and Expedite Development and Review of Certain New Drugs" and "Government Regulation – U.S. Government Regulation – New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension – Qualified Infectious Disease Product Exclusivity."

Prior to our involvement, DARE-BV1 was evaluated in an investigator-initiated proof-of-concept study that enrolled 30 women, ages 18 to 50, to assess its efficacy in treating bacterial vaginosis after a single administration. The study's primary efficacy endpoint was clinical cure based on the Amsel criteria at the test-of-cure evaluation visit, or Visit 2, which was approximately 7 to 14 days after administration of DARE-BV1. Of the 28 evaluable subjects, 24, or 86%, achieved clinical cure at Visit 2. The women were asked to return to the clinic for a third visit, or Visit 3, approximately 21 to 30 days following administration of DARE-BV1 to evaluate continued efficacy of treatment. Of the 24 subjects who completed Visit 2 and were deemed clinically cured, 23, or 96%, remained clinically cured at Visit 3. There were no reports of adverse reactions, including local reactions to DARE-BV1.

In December 2020, we announced positive topline results from our DARE-BVFREE Phase 3 clinical trial of DARE-BV1 for the treatment of bacterial vaginosis. As further discussed below, the study met its primary endpoint, demonstrating that a single administration of DARE-BV1 was superior to placebo as a primary therapeutic intervention for women diagnosed with bacterial vaginosis.

DARE-BVFREE was a randomized, multicenter, double-blind, placebo-controlled study that randomized 307 women diagnosed with bacterial vaginosis at 32 centers across the United States in a 2:1 ratio to receive a single vaginal dose of DARE-BV1 (clindamycin phosphate vaginal gel, 2%) (N=204) or a single vaginal dose of placebo gel (HEC Universal Placebo Gel) (N=103) to be applied intravaginally within one day of randomization. Subjects were

evaluated during three clinic visits: Day 1 (screening and randomization visit), Day 7-14 (assessment visit that occurred 7 to 14 days after study drug administration), and Day 21-30 (test-of-cure visit that occurred 21 to 30 days after study drug administration). The primary endpoint for the study was clinical cure of bacterial vaginosis determined at the Day 21-30 visit in the modified intent-to-treat (mITT) study population (N=180). In accordance with FDA guidance, the mITT population excludes subjects from the intent-to-treat (ITT) population (N=307) who subsequently demonstrated a positive test result for other concomitant vaginal or cervical infections at baseline. Clinical cure was defined as resolution of the specific clinical signs that comprise the Amsel criteria; specifically, resolution of abnormal vaginal discharge associated with bacterial vaginosis, clue cells less than 20% of total epithelial cells on microscopy, and a negative 10% KOH “whiff” test. The total study duration was approximately one month for each individual subject.

DARE-BV1 demonstrated statistically significant efficacy in the primary endpoint and in all five pre-specified secondary efficacy assessments. The clinical cure endpoint results are shown in the following table:

Summary of Clinical Cure Results (mITT Population), p-value < 0.001

	DARE-BV1 (N = 121)	Placebo (N = 59)
Clinical Cure at Day 7-14 visit	76.0%	23.7%
Clinical Cure at Day 21-30 visit (primary endpoint)	70.2%	35.6%

The clinical cure rate at the Day 21-30 visit for the ITT population was similar to that for the mITT population (70.1% for the DARE-BV1 group (N=204) and 36.9% for the placebo group (N=103), p-value < 0.001). The clinical cure rate at the Day 21-30 visit for the per protocol (PP) population was 77.2% for the DARE-BV1 group (N=101) and 42.6% for the placebo group (N=47). The PP population (N=148) means subjects from the mITT population who have no major protocol violations that impact the primary or secondary endpoints or who received any other bacterial vaginosis therapy for any reason. The clinical cure rate at the Day 7-14 visit for the PP population was 81.2% for the DARE-BV1 group (N=101) and 29.8% for the placebo group (N=47).

DARE-BV1 was well-tolerated in the study. There were no early discontinuations due to adverse events (AEs), and the only serious AE occurred in a woman in the placebo group. In the DARE-BV1 group, 15.3% of patients reported AEs that were considered to be possibly, probably or definitely related to study treatment compared to 9.7% of patients in the placebo group. Only two AEs were reported by more than 2% of patients in the DARE-BV1 group and at a rate higher than in patients in the placebo group – vulvovaginal candidiasis, commonly called a vaginal yeast infection (17.2% in the DARE-BV1 group and 3.9% in the placebo group), and vulvovaginal pruritus, commonly referred to as vaginal itching (4.4% in the DARE-BV1 group and 1.9% in the placebo group). Over half of the vaginal yeast infections reported in the DARE-BV1 group and exactly half of those reported in the placebo group occurred in patients who exhibited a positive yeast culture prior to dosing.

Based on the topline results from the DARE-BVFREE study and our meetings and other communications with the FDA since we announced those results, we plan to submit an NDA for DARE-BV1 for the treatment of bacterial vaginosis by the end of the second quarter of 2021. We have requested an application fee waiver for the NDA submission, using the small business eligibility criteria available under the Prescription Drug User Fee Act, or PDUFA, and anticipate that the FDA will grant that fee waiver. As discussed above, we intend to request priority review status for the NDA upon submission, which, if granted, could allow for a review period of six months from the FDA's receipt of our NDA submission, rather than the 10-month review period for non-priority submissions. Assuming we submit our DARE-BV1 NDA in the second quarter of 2021, the FDA grants priority review and sets a goal date for a decision, or a PDUFA date, within approximately six months from the NDA submission date, and the FDA approves the NDA in 2021, we would expect a commercial launch of DARE-BV1 in the United States in early 2022.

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) and with the potential to achieve “typical use” contraceptive efficacy comparable to current FDA-approved non-implanted hormonal contraceptive methods (pills, patches and vaginal rings), which is approximately 91% typical use efficacy. 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 a combination product and, following a request for designation process, the FDA designated the Center for Devices and Radiological Health, or CDRH, as the lead FDA program center for premarket review and product regulation. CDRH has determined that premarket approval will be required to market Ovaprene in the U.S.

In a postcoital test, or 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. 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.

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 sperm, and less than five PMS per HPF is considered indicative of contraceptive effectiveness.

Based on the positive results of our PCT clinical trial of Ovaprene, and with the support of Bayer under the commercial license agreement discussed below, we are conducting activities to support submission of an IDE to the FDA in the fourth quarter of 2021 for a pivotal clinical study of Ovaprene. We are designing the study to evaluate the safety and efficacy of Ovaprene to prevent pregnancy when used over a period of at least six months and up to approximately 12 months by approximately 250 women. We will seek to confirm alignment with the FDA on the study's design prior to commencement. Our ongoing communications with the FDA regarding the trial design include discussion of the amount of product use sufficient to demonstrate efficacy and safety (i.e., the number of study subjects to complete evaluation and the total number of menstrual cycles to be assessed using Ovaprene). We believe that the development activities we are conducting prior to commencement of the planned pivotal study will continue to advance this program and enable a study start by the first quarter of 2022 and a six-month safety and efficacy data readout by year-end 2022. If the planned pivotal clinical study is successful, we expect the study's data to support a PMA submission to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

We are developing Ovaprene with ADVA-Tec, Inc. and Bayer HealthCare LLC, or Bayer, as part of two strategic collaborations announced in March 2017 and January 2020, respectively. See "License Agreements" 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 in men, women continue to lack effective options for female sexual arousal disorder, or FSAD, the most analogous condition of the various types of female sexual dysfunction disorders. We are developing Sildenafil Cream, 3.6%, 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 vulva and vagina for treatment of FSAD. Today, there are no FDA-approved products that specifically address the symptoms or underlying pathology of FSAD. 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, 3.6% in the U.S. for the treatment of women suffering from FSAD. If approved, Sildenafil Cream, 3.6% could be the first FDA-approved FSAD treatment option for women.

FSAD 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, which is characterized primarily by a lack of sexual desire. As with erectile dysfunction in men, FSAD in women is associated with insufficient blood flow to the genitalia. Sildenafil Cream, 3.6% 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.

In a Phase 1 clinical study 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 post-menopausal 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 safe and 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, women with FSAD, ages 21 to 60, received a single 2 g dose of Sildenafil Cream, 3.6%. Of the 35 women enrolled, 31 (15 pre-menopausal and 16 post-menopausal) completed the study. The primary objective was to evaluate the efficacy of Sildenafil Cream, 3.6% compared to placebo cream assessed by participant-reported levels of subjective cognitive sexual arousal and by physiological genital arousal response. Sildenafil Cream, 3.6% 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.

A Phase 1, single-dose, double-blind, placebo-controlled, two-way crossover study to evaluate the feasibility of using thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% 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, 3.6% 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, 3.6% visits compared to placebo cream visits.

In 2019, as part of our Phase 2b clinical program for Sildenafil Cream, 3.6%, 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 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 March 2021, we announced initiation of our Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% in women with FSAD and that we are targeting a topline data readout by year-end 2021. During the planned Phase 2b RESPOND clinical trial, subjects will use Sildenafil Cream, 3.6% and placebo cream in their home setting and will document genital arousal symptoms and distress using PRO instruments. The primary efficacy endpoint of the study

is a composite endpoint that includes patient-reported improvement in genital sensations of arousal and reduction in distress associated with FSAD. The Phase 2b RESPOND trial is designed to evaluate Sildenafil Cream, 3.6% compared to placebo cream over 12 weeks of dosing following both a non-drug and placebo run-in period. The Phase 2b RESPOND study is expected to randomize 400 to 590 subjects into the double-blind dosing period from 40 to 50 sites in the U.S. to ensure a total of 300 (150:150) to 440 (220:220) subjects complete the 12-week double-blind dosing period. The final study sample size will be determined by a single interim analysis for unblinded sample size re-estimation, based on the study's adaptive design. An adaptive design implemented in accordance with the FDA's Guidance for Industry on adaptive designs for clinical trials of drugs mitigates the risk of the study being underpowered if the true treatment effect and variability are significantly different from estimates based on published data but are still clinically meaningful. Our target timeline for topline data readout of the Phase 2b RESPOND study assumes that enrollment proceeds successfully and that an increase in sample size above 400 randomized subjects is not required.

We will continue to actively engage with the FDA in 2021 to help ensure that any additional required studies and development activities may be completed during the course of the clinical development program to support an NDA submission.

We are developing Sildenafil Cream, 3.6% with Strategic Science & Technologies-D LLC under our license and collaboration agreement announced in February 2018. See "License Agreements" below for discussion of the terms of this collaboration.

DARE-HRT1

DARE-HRT1 is a unique IVR containing bio-identical estradiol and bio-identical progesterone that is designed to be worn over multiple weeks for sustained drug delivery for the treatment of vasomotor and vaginal symptoms associated with menopause as part of a 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, commonly referred to as hot flashes, and the genitourinary syndrome of menopause, and it has been shown to prevent bone loss and fracture. 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. We intend to leverage the existing safety and efficacy data on the active ingredients in DARE-HRT1, estradiol and progesterone, to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-HRT1 in the U.S.

In July 2020, our wholly-owned Australian subsidiary commenced a Phase 1 open-label, three-arm, parallel group clinical study of DARE-HRT1 to evaluate the pharmacokinetics, or PK, and safety of DARE-HRT1 in approximately 30 healthy, post-menopausal women at specialty women's health sites in Australia. The primary objective of the study is to describe the PK parameters of two different dose combinations (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) over 28 days. Secondary endpoints of the study include assessing the safety and tolerability of DARE-HRT1 and comparing the exposure of estradiol, estrone, and progesterone of DARE-HRT1 over 28 days against a daily combination of oral estrogen (Estrofem®) and oral progesterone (Prometrium®). We completed enrollment in the study in March 2021 and anticipate reporting topline data in the second quarter of 2021.

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

DARE-FRT1

DARE-FRT1 is an IVR designed to deliver bio-identical progesterone over a 14-day period and is being developed for the prevention of preterm birth and for broader luteal phase support as part of an in vitro fertilization, or IVF, treatment plan. DARE-FRT1 was developed from the same IVR technology platform as DARE-HRT1. We plan to continue to conduct development activities for DARE-FRT1 in preparation for a Phase 1 clinical trial anticipated to start in 2022. The timing and availability of additional funding will impact the timing of initiation of a Phase 1 clinical study of DARE-FRT1. 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 in the U.S.

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

DARE-VVA1

DARE-VVA1 is a proprietary formulation of tamoxifen for vaginal administration. We are developing DARE-VVA1 as an alternative to estrogen-based therapies for the treatment of vulvar and vaginal atrophy, or VVA, in women with or at risk for hormone-receptor positive (HR+) breast cancer, including women on anti-cancer therapy, to treat the symptoms of VVA. Tamoxifen is a well-known and well-characterized selective estrogen receptor modulator, or SERM. Tamoxifen has unique properties that produce different effects in different types of tissues. In breast tissue, tamoxifen acts as an estrogen antagonist, meaning that it can inhibit estrogen's effect and hence why it may be effective in treating HR+ breast cancer. However, in other tissue, including vaginal tissue, tamoxifen has been reported to exert an estrogen-like response. This has the potential to have a favorable effect on vaginal cytology. VVA is an inflammation of the vaginal epithelium due to the reduction in levels of circulating estrogen, which is characterized by pain during intercourse, vaginal dryness and irritation. Commonly used therapies for VVA are estrogen-based and 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. Due to the prevalence of aromatase inhibitors for the treatment of HR+ breast cancer, the prevalence of VVA in post-menopausal breast cancer patients is estimated to be between 42 and 70 percent. We plan to continue to conduct development activities for DARE-VVA1 in preparation for a Phase 1 clinical trial anticipated to start during the second half of 2021. The timing and availability of additional funding will impact the timing of initiation of a Phase 1 clinical study of DARE-VVA1. 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.

Sales and Marketing

We currently have no formal internal marketing or sales infrastructure or capabilities. To commercialize our products, if and when our product candidates are approved, we expect to enter into agreements with companies with established marketing, sales and distribution capabilities in women's health in order to supplement our internal marketing or sales efforts. Such arrangements may include granting pharmaceutical companies with other commercial products in women's health out-licenses to exclusively market, sell and distribute our products in specific geographies, engaging commercial sales organizations to utilize their internal sales organizations and other commercial functions for market access, marketing, distribution, and other related services, or assembling a hybrid of these potential options to co-promote our products.

In January 2020, we entered into an exclusive license agreement with Bayer for the commercialization of Ovaprene in the U.S. See “License Agreements” below for discussion of the terms of this collaboration.

Manufacturing and Suppliers

We do not own or operate, nor do we currently plan to establish, manufacturing facilities for the production of our product candidates. We rely on third-party contract manufacturers, or CMOs, to provide all the material and supplies for our nonclinical and clinical studies, and, if our product candidates receive regulatory approval, we expect to rely on CMOs to produce commercial quantities of our products, as well as the raw materials, drug substances, excipients and other supplies required to produce the finished products. These arrangements allow us to maintain a smaller and more flexible infrastructure.

We have no long-term arrangements for the production or supply of our product candidates or the materials required to produce them, except with respect to Ovaprene and Sildenafil Cream, 3.6%. Under our agreements with ADVA-Tec and SST, respectively, ADVA-Tec is responsible for providing all clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, and SST is responsible for providing Sildenafil Cream, 3.6% for the planned Phase 2b clinical study. For further clinical development, we plan to utilize CMOs to produce and supply Sildenafil Cream, 3.6%. As we advance our product candidates toward regulatory approval, we intend to identify, qualify and enter into long-term arrangements with CMOs for commercial production of each approved product.

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, for some key raw materials or components of our clinical-stage product candidates, including Ovaprene and Sildenafil Cream, 3.6%, alternative supply sources may not be readily available. See ITEM 1A. "RISK FACTORS – Risks Related to our Business – Our success relies on third-party suppliers and manufacturers of our product candidates, including multiple single source suppliers and manufacturers," below.

License Agreements

Hammock/MilanaPharm Assignment and License 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 DARE-BV1, 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.

The following is a summary of other terms of the License Amendment, as amended:

License Fees. A total of $235,000 in license fees were payable, and were paid, to MilanaPharm: (1) $25,000 in connection with the execution of the License Amendment; (2) $100,000 in 2019; and (3) $110,000 in 2020.

Milestone Payments. We will pay to MilanaPharm: (1) up to $300,000 in the aggregate upon achievement of certain clinical and regulatory development milestones, $50,000 of which was paid in 2020, and (2) up to $1.75 million in the aggregate upon achieving certain commercial sales milestones.

Foreign Sublicense Income. We will pay MilanaPharm 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, we will pay MilanaPharm 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.

The following is a summary of other terms of the 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.

Fees. A total of $512,500 in fees were payable, and were paid, to Hammock: (1) $250,000 in connection with the execution of the Assignment Agreement; (2) $125,000 in 2019; and (3) $137,500 in 2020.

Milestone Payments. We will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones.

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.

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 under ADVA-Tec's intellectual property rights to develop and commercialize Ovaprene for human contraceptive use worldwide. ADVA-Tec and its affiliates own issued patents or patent applications covering Ovaprene, and control proprietary trade secrets covering the manufacture of Ovaprene. As of March 29, 2021, this patent portfolio includes nine issued U.S. patents, one pending U.S. patent applications, eight granted foreign patents, including four European patents, and seven pending foreign patent applications, all of which are exclusively licensed to us for all uses of Ovaprene as a human contraceptive device. Under this license agreement, we have a right of first refusal to license these patents and patent applications for additional indications.

The following is a summary of other terms of the ADVA-Tec license agreement:

Research and Development. ADVA-Tec will conduct certain research and development work as necessary to allow us to seek a PMA from the FDA and will provide us with clinical supplies of Ovaprene for clinical and commercial use on commercially reasonable terms. We must use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, and $5 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

Milestone and Royalty Payments. We will pay to ADVA-Tec: (1) up to $14.6 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 development and regulatory milestones include: the completion of a successful postcoital clinical study; the FDA's approval to commence a pivotal clinical trial; successful completion of such 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. Because future milestone payments depend upon the successful progress of our product development programs, we cannot estimate with certainty when these payments will occur.

Royalty Payments. After the commercial launch of Ovaprene, we will pay to ADVA-Tec 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.

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, (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, or (5) enroll a patient in the first non-significant risk medical device study or clinical trial as allowed by an institutional review board within six months of the production and release of Ovaprene, unless such failure is caused by events outside of the our reasonable control.

Bayer HealthCare LLC 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 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.

The following is a summary of the other terms of the Bayer license agreement:

Milestone Payments Paid 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.

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.

SST License and Collaboration Agreement

In February 2018, we entered into a license and collaboration agreement with Strategic Science and 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, 3.6% 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.

The following is a summary of other terms of the SST license agreement:

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 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.

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. We are entitled to sublicense the rights granted to us under this agreement.

The following is a summary of other terms of the Catalent license agreement:

Upfront Fee. We paid a $250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement.

Annual Maintenance Fee. We will pay an annual license maintenance fee to Catalent on each anniversary of the date of the agreement, the amount of which will be $50,000 for the first two years, and $100,000 thereafter, and which 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. We made the first of these payments in April 2019.

Milestone Payments. We must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the agreement.

Royalty Payments. During the royalty term, we will pay Catalent 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.

Microchips Acquisition

In November 2019, we acquired Microchips Biotech, Inc., or Microchips, via a merger transaction in which a wholly owned subsidiary we formed for purposes of this transaction merged with and into Microchips, and Microchips survived as our wholly owned subsidiary. Microchips is developing a proprietary, implantable drug delivery system designed to store and precisely deliver numerous therapeutic doses over months and years on a schedule determined by the user and controlled via wireless remote. Microchips' lead product candidate is a pre-clinical stage contraceptive application of the technology that utilizes levonorgestrel, now known as DARE-LARC1.

At the closing of the merger, we issued an aggregate of approximately 3.0 million shares of our common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger. Such shares were in consideration of Microchips' cash and cash equivalents, less liabilities, at closing. Microchips' cash and cash equivalents at closing were approximately $5.9 million after taking into account payment of transaction-related expenses.

We agreed to pay the following contingent consideration to the former Microchips 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 we acquired in the merger; (c) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. We agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to the implantable contraceptive product in development by Microchips. We recorded $1.0 million in contingent consideration associated with the milestone payments that we expect to become payable in the first half of 2021, and if and when they become due and payable, we may make such milestone payments in cash, shares of our common stock or some combination of both.

The shares of our common stock issued at the closing of the Microchips merger are being held, and any contingent consideration that becomes payable during the 18-month period following the closing will be held, in escrow for a period of 18 months post-closing to satisfy the indemnification obligations, if any, of the former Microchips stockholders under the merger agreement. That 18-month period will expire in May 2021. We agreed to register the shares of our common stock issued at the closing as well as any shares issuable after the closing as contingent consideration to the former Microchips stockholders for resale under the Securities Act of 1933, as amended, or the Securities Act. A registration statement on Form S-3 registering the possible resale from time to time of up to approximately 5.0 million shares of our common stock by the former Microchips stockholders, including the shares we issued at the closing of the merger, became effective on June 8, 2020.

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 DARE-BV1, we are the exclusive licensee of two issued U.S. patents set to expire in December 2028, subject to any extensions or disclaimers, and two 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. In addition, we have rights to three pending foreign patent applications and one pending U.S patent application. If issued the patent term for these patents would be expected to expire in 2036, subject to any extensions or disclaimers.

Under the terms of the ADVA-Tec license agreement, regarding Ovaprene, we are the exclusive licensee of nine granted U.S. patents, one pending U.S. patent application, eight granted foreign patents, including four EPO patents validated in a total of 55 countries, and seven pending foreign patent applications. Two of the patents that are particularly important to the protection of Ovaprene 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.

Under the terms of the SST license agreement, regarding Sidenafil Cream, 3.6%, we are the exclusive licensee in the Field of Use of 19 issued patents worldwide (nine U.S. patents and 10 foreign patents, including two EPO patents validated in a total of 24 countries). Additionally, there is one patent application pending in the US, one in Europe, and three 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 through that is set to expire in late 2031, each of such terms being subject to any future extensions of disclaimers.

Under the terms of the Catalent license agreement, regarding our intravaginal ring platform which includes DARE-HRT1, we are the exclusive licensee of four issued U.S. patents with patent terms set to expire in April 2024, November 2024, February 2025, and September 2027, including patent term adjustment, four issued foreign patents with patent terms until April 2024, including one European patent validated in three countries, as well as one pending U.S. application and two pending foreign applications that if granted are expected to have patent terms that expire in May 2038, subject to any extensions or disclaimers.

When we acquired Pear Tree Pharmaceuticals, Inc. in April 2018, regarding DARE-VVA1, we obtained the rights to three U.S. patents and one Japanese patent. The patent term 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.

When we acquired Microchips Biotech, Inc. in November 2019, we obtained the rights to over 100 patents and applications. The key technology underlying the platform is supported by 21 U.S. patents and 42 foreign patents, including six EPO patents validated in various European countries, and 16 pending patent applications, including three U.S. applications and 13 international applications. We believe that the three most recently granted patent families are most directly applicable to our DARE-LARC1 program. Those patent families have patent terms that are set to expire 2032, 2033, and 2034 respectively, subject to any extensions or disclaimers. These patent families include patents granted in the U.S., E.U. and other key international markets. One pending patent application related to DARE-LARC1, if granted, would have a patent term that would be expected to expire in 2040, subject to any extensions or disclaimers.

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. In accordance with the terms of the ADVA-Tec license agreement, we are the exclusive licensee of the Ovaprene registered trademark.

Pre-Clinical Programs

In addition to our clinical-stage product candidates, we have licenses or other rights to the following pre-clinical stage product candidates in women's health that meet our selection criteria of technology or product candidates with potential to expand options, improve outcomes, and facilitate convenience for women:

- **DARE-LARC1**, a combination product designed to provide long-acting, reversible contraception comprising an implantable, user-controlled wireless drug delivery system and levonorgestrel;
- **ORB-204 and ORB-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

Competition

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology and medical device) are highly competitive and subject to rapid and significant change. We may not compete successfully against organizations with competitive products, particularly large pharmaceutical companies. 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 our Business—*The product candidates we are developing or may develop are likely to face significant competition and our business and operating results will suffer if we fail to compete effectively*," below.

We expect that, if approved, DARE-BV1 will compete 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. Branded, single-dose FDA-approved products for bacterial vaginosis include Solosec® (secnidazole) oral granules manufactured for and distributed by Lupin Pharmaceuticals, Inc., Clindesse® (clindamycin phosphate) vaginal cream, 2% manufactured and distributed by Perrigo, and Nuvessa™ (metronidazole vaginal gel 1.3%) distributed by Exeltis USA, Inc.

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 IUDs, spermicides and vaginal gels, as well as hormonal products such as pills, patches, vaginal rings 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, 3.6% has the potential to be the first FDA-approved product for the treatment of FSAD.

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 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, the efficacy and safety of our products (alone and relative to other treatment options), the degree of patent or other protection afforded to particular products, and reimbursement for use of those products.

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, 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 a 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 cGMPs, 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. Preclinical 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.

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 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.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA 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 a 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 complete response letter 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 ("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.

FDASIA also included the Generating Antibiotics Incentives Now Act, or the GAIN Act, which directed FDA to implement 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. There also are continuing, annual user fee requirements for that are now assessed as program fees for certain NDA-approved drugs. The most recent, 2017 reauthorization of PDUFA restructured the prescription drug user fee program to eliminate the previously collected establishment and supplemental application fees.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. 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 cGMPs 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 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 most recent of which is still in the process of being phased in to the U.S. supply chain and regulatory framework. 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. Congress more recently enacted the Drug Supply Chain Security Act, or DSCSA, which made significant amendments to the FDCA, including by replacing certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme. The DSCSA now requires uniform national standards for wholesale distribution and, for the first time, for third-party logistics providers; it also provides for preemption of certain state laws in the areas of licensure and prescription drug traceability. The comprehensive system envisioned by this law is being implemented both by the FDA and those various stakeholders towards the shared goal of building an interoperable electronic system to identify and trace prescription drugs distributed in the United States for enhanced supply chain security. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, repackagers, wholesale distributors, and dispensers (primarily pharmacies) over a 10-year period that is expected to culminate in November 2023.

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 premarket approval application, or 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 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.

Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure 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.

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 the FDA may request such data. 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 those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. 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, preclinical, 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 sufficiently complete, the FDA will accept the application 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 premarket approval applications or premarket approval application 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.

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. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under the provisions enacted under FDASIA, the FDA is required 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 2021, FDA will attempt to issue a decision on 65% 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* reclassification 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) pre-market 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 are approved by a duly-appointed IRB at each clinical trial site.

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;
- unannounced routine or for-cause device facility inspections by the FDA;
- labeling regulations, which prohibit the promotion of products 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 products;
- 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, pre-scheduled and 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 components or products, e.g., drug-device or biologic-device. Such products often raise regulatory, policy and review management challenges because they integrate components 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 component 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 comprised of two or more regulated components 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* reclassification 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, it may request that the agency reconsider that 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 the 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 of 2002.

Since a combination product incorporates two or more components that have different regulatory requirements, a combination product manufacturer must comply with all cGMP and QSR requirements that apply to each component. 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 component included in the combination product; or (2) either the drug cGMPs 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, which became law in December 2016 and, among other things, amended provisions of the FDCA, clarified that for drug-device combination products comprising an FDA-approved drug and device primary mode of action, Hatch-Waxman Act requirements apply. Accordingly, a potential patent dispute regarding the listed drug that is being referenced by the combination product sponsor may result in the delay of the 510(k) clearance or PMA approval 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 primary mode of action.

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 its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as 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.

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 both NIH and the FDA have recently signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Other U.S. Health Care Laws and Compliance Requirements

In addition to FDA requirements, several other types of state and federal laws apply and will apply to our operations. These laws include, among others, health care information and data privacy protection 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 healthcare 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 healthcare 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 healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare 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 healthcare 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, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, 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 transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that 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 possibly other persons, 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
- 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 complicating compliance efforts. 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.

Moreover, in November 2020, the U.S. Department of Health and Human Services finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the Physician Self-Referral Law (Stark Law) and the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

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 expect to develop a compliance program 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 healthcare 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 healthcare laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, 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, healthcare 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 healthcare 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 healthcare 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 U.S., 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. Accordingly, 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 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 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. 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 pharmaceutical benefit managers, or PBMs, 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 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, any or all of which may affect our business.

Since its enactment there have been judicial and congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Certain members of the U.S. Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the ACA. While Congress has to date not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In December 2019, the Fifth Circuit Court of Appeals upheld a district court's finding that the individual mandate in the ACA is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the ACA, but not specifically related to the individual mandate or health insurance, could be severed from the rest of the ACA so as not to have the law declared invalid in its entirety. In March 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case and, in November 2020, heard oral arguments. A decision from the Supreme Court is expected to be issued in spring 2021. It is unclear how this litigation and other efforts to repeal and replace the ACA will affect the implementation of that law, the pharmaceutical industry more generally, and our business. We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which

was signed into law on March 27, 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The 2021 Consolidated Appropriations Act was subsequently signed into law on December 27, 2020 and extends the CARES Act suspension period to March 31, 2021.

The Biden Administration, which assumed control of the Executive Branch on January 20, 2021, has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful, 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.

Data Privacy and the Protection of Personal Information

We are subject to laws and regulations governing data privacy and the protection of personal information including health 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. 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 health information that is protected under HIPAA, called “protected health information,” 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.

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 recently adopted the California Consumer Privacy Act of 2018, or CCPA. 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, and creating 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. Additionally, 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 will modify 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. Other states in the U.S. are considering privacy laws similar to CCPA. In February 2021, the Virginia legislature became the second to enact a state-specific law called the Consumer Data Protection Act, which includes key differences from California’s law, further complicating compliance by industry and other stakeholders.

Health Care Reform and Potential Changes to Laws and Regulations

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. For example, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA’s user fee programs and included additional drug and device provisions that build on the Cures Act enacted in December 2016. 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. For example, the 2020 Consolidated Appropriations Act (P.L. 116-94) included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS program for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

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 has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an EU member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial applications must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents. In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted and it is anticipated to come into application in late 2021. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend 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"; 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, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

To obtain marketing approval of a drug in the EU, an applicant must submit an 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.

In addition, medical devices marketed in Europe currently are 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 directives and standards regulate 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 varies depending on the class of the product, but normally involves 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. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the EU.

In 2017, European Union regulatory bodies finalized a new Medical Device Regulation ("MDR"), which replaced the existing MDD framework and 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 European Parliament voted in April 2020 to postpone implementation of the MDR by one year, giving the medical device industry and Notified Bodies until May 26, 2021 to come into compliance assuming no additional delays are needed. The MDR changes several aspects of the existing regulatory framework for medical device marketing in Europe and is expected to result in 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.

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 and Australia, 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 GMPs 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; 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; 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 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 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 calls into question certain data transfer mechanisms as between the EU member states and the U.S. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business and future actions of EU data protection authorities are difficult to predict. Consequently, there is some risk of any data transfers from the European Union being halted. 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 healthcare 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 29, 2021, we had 23 employees. Sixteen of our employees are full-time and seven are part-time employees, 12 are in research and development and 11 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 will enable 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.

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 and our other public filings, before making investment decisions regarding our securities.

- We will need to raise additional capital to continue our operations and remain a going concern, and our ability to do so may be limited and more expensive due to low trading volume, price or market capitalization, our lack of revenue, net losses and limited operating history, and/or applicable laws and regulations. If we fail to obtain additional capital, we will be unable to complete development or obtain regulatory approval for commercialization of our product candidates.
- We have a limited operating history, have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources and substantial capital requirements, make it difficult to assess our prospects.
- The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs.
- We may not receive any additional payments under our license agreement with Bayer, and Bayer may terminate the agreement at any time without cause upon limited prior notice.
- Due in part to our limited financial resources, we may fail to effectively develop the product candidates in our portfolio and execute our current product development plans, including the commencement and completion of clinical trials and regulatory submissions, in accordance with our current timeline expectations.
- We depend heavily on the success of our lead product candidates, DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%. 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 any of these product candidates on our anticipated timelines, or at all, could have a material adverse effect on our business, operating results and financial condition.
- We have a relatively small number of employees and if we fail to attract and retain key personnel, we may not successfully complete development of, obtain regulatory approval for or commercialize our product candidates, or otherwise implement our business plan.
- We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our product development programs, including the conduct of our clinical and non-clinical studies and the supply and manufacture of our product candidates. Failure of these third parties, including multiple single source suppliers and manufacturers, 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.
- 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.
- Our business depends on obtaining the approval of regulatory authorities, and in particular, FDA approval, for our product candidates in a timely manner, and the requirements or pathways for obtaining approval for our product candidates may change over time, requiring more financial resources and development time than we currently anticipate.

- Our business strategy is to establish and leverage strategic partnerships to achieve commercialization of our product candidates, if approved. We have no internal sales, marketing or distribution capabilities. Under any such collaborations, we may not have control over several key elements relating to the development and commercialization of our product candidates, and any failure by such third parties to adequately perform their obligations under our agreements could negatively impact our business, operating results and financial condition.
- The product candidates we are developing or may develop are likely to face significant competition. If we receive marketing approval for any of our product candidates, their ability to compete and potential to generate revenue will be impacted by the efficacy and safety outcomes of our clinical trials, the label claims that the FDA or other regulatory authorities approve for the product, and the degree of acceptance among the medical community and consumers and their preference of our products over available alternative products.
- Even if we obtain regulatory approval in the United States or elsewhere to market any of our products, the reimbursement environment at the time of approval may hurt our financial prospects. If the out-of-pocket costs for our products are deemed by women to be unaffordable, a commercial market may never develop.
- The loss or impairment of our rights under any license agreement for our lead product candidates could prevent us from developing or commercializing them, which would have a material adverse effect on our business prospects, operations and viability.
- Our failure to adequately protect or enforce our and our licensors' intellectual property rights could materially harm our proprietary position in the marketplace or prevent or impede the commercialization of our current and potential future products.
- Lack of patent protection for the active ingredients in certain of our product candidates, including DARE-BV1 and Sildenafil Cream, 3.6%, may limit the commercial opportunity for those products if competitors are able to develop and commercialize safe and effective alternative formulations or methods of delivery of the active ingredients.
- The price of our common stock has been and may continue to be highly volatile and such volatility could be unrelated to our performance and operating results. Volatility in our market price may subject us to increased risk of securities litigation, including class-action lawsuits, which could be expensive and divert management attention.
- There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market, and such failure could result in the suspension or delisting of our common stock, which could, among other things, 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.
- Future sales and issuances of our equity, including sales and issuances of our common stock in at the market, or ATM, offerings through a sales agent, under our purchase agreement with Lincoln Park and upon exercise of our stock options and warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock, even if our business is doing well.
- Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our third-party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information 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 Business

We will need to raise additional capital to continue our operations and execute our current product development plans.

We expect that our net losses will continue for the foreseeable future as we develop and seek to bring to market our existing product candidates and potentially acquire, license and develop additional product candidates. Advancing our portfolio of innovative investigational products for women's health through clinical development and pursuing regulatory approval will require substantial additional investment. We currently do not have the capital necessary to advance all of our product candidates through research and clinical development and regulatory approval. Our ability to continue as a going concern depends on our ability to raise additional capital through financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements, to successfully execute our current operating plan and to continue the development of our current product candidates. This report includes disclosures and an opinion from our independent registered public accounting firm stating that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2020 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.

Our capital needs have been and will continue to depend highly on the product development programs we choose to pursue, the progress of these programs, including the number, size, timing, rate of patient recruitment, duration of patient treatment and follow-up and the results of our clinical trials and pre-clinical studies, the cost and timing of development and supply of material for our clinical trials and pre-clinical studies, the cost, timing and outcomes of regulatory submissions and decisions regarding a potential approval for any one or more of our current or future product candidates we may choose to develop, and the terms of our contracts with service providers and license partners. In addition, the development of our clinical-stage candidates and the advancement of our pre-clinical product candidates will depend on results of ongoing and upcoming clinical trials and pre-clinical testing and our financial resources at the time of such results. 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, or should the duration of our planned and ongoing clinical trials be longer than anticipated due to difficulties in patient recruitment or otherwise, our cash resources will be further strained. Should our product development efforts succeed, we will need to develop a commercialization plan for each product developed, which may also require significant resources to develop and implement.

At December 31, 2020, our cash and cash equivalents were approximately $4.7 million and our accumulated deficit was approximately $71.4 million. We incurred a net loss of approximately $27.4 million for the year ended December 31, 2020. We may never become profitable. We expect negative cash flows from our operations to continue for the foreseeable future. Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over the next 12 months from the date of issuance of the accompanying consolidated financial statements unless we raise additional capital or significantly curtail our operations. We must raise additional capital to finance our operations and remain a going concern.

Additional capital may not be available to us, or even if it is, the cost of such capital may be high. We may be forced to obtain additional capital before reaching clinical and/or regulatory milestones, when our stock price or trading volume or both are low, or when the general market for life sciences companies is weak. Raising capital under any of these or similar scenarios, if we can raise any at all, may lead to significant dilution to our existing stockholders. See also "Our ability to raise capital may be limited by laws and regulations" and "We are heavily reliant on our ability to raise capital through capital market transactions. A low trading volume, price and market capitalization together with our lack of revenue, net losses and limited operating history may make it difficult and expensive for us to raise additional capital" below.

If we raise capital through collaborations, strategic alliances or other similar types of arrangements, we may have to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates we would otherwise seek to develop or commercialize. In addition, we may enter into collaborations, such as our license agreement with Bayer, that do not provide significant near-term or guaranteed funding, thus requiring that we continue to seek to raise additional capital to fund product development through other means. See also "We may not receive any additional payments under our license agreement with Bayer, and Bayer may terminate the agreement at any time without cause upon limited prior notice," below. Further, the COVID-19 pandemic may adversely affect our ability

to enter into strategic collaborations for development and/or commercialization of our product candidates. Operational disruptions, resource constraints or shifts in business strategy of potential partners as a result of the COVID-19 pandemic may adversely affect collaboration opportunities for our product candidates. See also "The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs," below.

There can be no assurance that we can raise capital when needed or on terms favorable to us and our stockholders. With the potential to significantly affect investor sentiment and increase market volatility, the COVID-19 pandemic and measures taken by federal, state and local governments to reduce the spread of COVID-19, increase uncertainty around our ability to access the capital markets when needed and on acceptable terms. If we cannot raise capital when needed on acceptable terms, or at all, we will not be able to advance our product candidates as currently planned or grow our product portfolio, we will need to reevaluate our planned operations, we may relinquish rights under our license agreements with third parties relating to our product candidates, and we may need to delay, scale back or eliminate some or all of our development programs, reduce expenses or cease operations, any of which would have a significant negative impact on our prospects and financial condition, as well as the trading price of our common stock. Moreover, if we are unable to obtain additional funds on a timely basis, there will be an increased risk of insolvency and up to a total loss of investment by our stockholders.

We have a limited operating history, have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources and substantial capital requirements, make it difficult to assess our prospects.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which to evaluate our business and prospects. Development of drug and drug/device combination products is a highly speculative, lengthy and expensive undertaking and involves substantial risk. To date, 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 have devoted significant resources to acquiring our portfolio of product candidates and to research and development, or R&D, activities for our product candidates. Since inception, we have incurred significant operating losses. As discussed above, we must raise additional capital to finance our operations and remain a going concern.

The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs.

The COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain a rapidly evolving and uncertain risk to our business, operating results, financial condition and stock price. In large part, the extent to which the pandemic affects us will depend on future developments that are beyond our knowledge or control, including, but not limited to, the duration and severity of the pandemic, governmental and individual organization actions and policies implemented to reduce transmission of the disease, and the speed with which and degree to which normal economic and operating conditions resume.

The longer the pandemic persists, the greater the potential for significant adverse impact to our business operations and those of the contract research organizations (CROs), contract manufacturing organizations (CMOs) and other third-party consultants and vendors on which we depend to, among other things, conduct our clinical and nonclinical studies, supply our clinical trial materials, and assist with regulatory affairs necessary to advance our programs. Employee and family member illness, increased childcare and elder care responsibilities, and quarantines, travel restrictions, prohibitions on non-essential gatherings, shelter-in-place orders and other similar directives and policies intended to reduce the spread of the disease, may reduce our productivity and that of the third parties on which we rely and may disrupt and delay many aspects of our business, including R&D activities, production and supply of clinical trial materials and regulatory affairs activities. As a result of resource constraints, third parties on which we rely may not meet their contractual obligations to us or may allocate constrained resources to projects other than ours, any of which could significantly increase the cost and timelines for our development programs. In addition, the increase in personnel working remotely, both ours and those of the third parties on which we rely, could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could significantly adversely impact our business operations or significantly delay necessary interactions with the FDA and other regulatory agencies, our CROs and CMOs, clinical trial sites, current and potential collaborators, and other third parties.

The COVID-19 pandemic could cause delays in current timelines for our ongoing and planned clinical studies, our regulatory submissions and potential marketing approvals and, ultimately, commercial launch of any approved product. One or more of the clinical and regulatory milestones we anticipate will occur in 2021 or 2022 may be delayed or otherwise adversely impacted as a result of the pandemic. For example, clinical trial site initiation and/or patient enrollment may be significantly delayed or suspended as a result of personnel and other resource constraints

of healthcare providers, as well as adherence to governmental orders and internal policies intended to reduce the spread of COVID-19. In addition, we may experience lower than anticipated subject enrollment and completion rates, including because individuals may avoid medical settings, particularly for non-critical conditions, due to concerns of contracting COVID-19 or due to shelter-in-place and social distancing orders.

In addition, the pandemic has resulted in disruption and volatility in the global capital markets, and while the longer-term economic impact is difficult to assess and predict at this time, it could negatively impact our ability to access additional capital when needed or on terms favorable to us and our stockholders. If we cannot raise capital when needed on acceptable terms, or at all, we will not be able to continue development of our product candidates as currently planned or at all, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our development programs, reduce expenses or cease operations, any of which could have a significant negative impact on our prospects and financial condition, as well as the trading price of our common stock.

A key aspect of our business strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize our product candidates. As a result of the pandemic, potential and current partners may experience operational disruptions and financial and other resource constraints and implement new strategic plans that delay or reduce their efforts in the women's health in general or in our programs in particular, which could adversely affect our ability to enter into or maintain collaborations, strategic alliances or other similar types of arrangements and may result in or contribute to disruption and delays in later-stage clinical development and, if approved, commercial launch of our product candidates. We do not have, and do not currently plan to develop, the internal sales, marketing and distribution infrastructure necessary to independently market and sell our product candidates, if approved.

To help mitigate the impact of the pandemic on our business, we developed a plan with our third-party service providers designed to address the challenges and risks presented by the pandemic on our ongoing clinical trials, and we developed a plan designed to protect the safety, health and well-being of our employees while maintaining employee productivity. However, there can be no assurance that such plans will be effective in mitigating the potential adverse effects of the pandemic on our ongoing and planned clinical trials and nonclinical studies, on the productivity of our employees or on our business, financial condition and results of operations.

The extent to which the pandemic and efforts to reduce its spread impact our business, financial condition and results of operations is uncertain and cannot be predicted with reasonable accuracy at this time and will depend on future developments that are also uncertain and cannot be predicted with reasonable accuracy at this time, including new information that may emerge concerning the degree to which COVID-19 is contagious and virulent, the effect of actions taken in the United States and other countries to contain and treat COVID-19, the rate and efficacy of vaccinations against COVID-19, and further actions implemented to contain and treat the disease and its impact, among others.

The COVID-19 pandemic may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

We may not receive any additional payments under our license agreement with Bayer, and Bayer may terminate the agreement at any time without cause upon limited prior notice.

In January 2020, we entered into an exclusive license agreement with Bayer for the commercialization of Ovaprene in the U.S. Under our agreement, Bayer will have no future 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. Should Bayer elect to do so, it must pay us an additional $20.0 million (the "Clinical Trial and Manufacturing Activities Fee"). If we do not successfully complete clinical development 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 decide not to pay the Clinical Trial and Manufacturing Activities Fee regardless of the outcome of the pivotal clinical trial. Further, Bayer may elect to terminate the license agreement without cause at any time upon 90 days' prior notice. If the license grant does not become effective or if Bayer terminates the agreement, our ability to complete development of and commercialize Ovaprene may be significantly impaired and it could have material adverse effect on our business and prospects in general and on our stock price.

If Bayer elects to make the license grant effective, it will obtain exclusive rights to commercialize Ovaprene in the U.S. In this case, Ovaprene's value to us will be generated through royalties on net sales and achievement of commercial milestones. If Bayer is not successful or has limited success in commercializing Ovaprene, Ovaprene's value to us will be significantly impaired. We may realize only a small fraction of the potential value of the license agreement. Other than the upfront fee, the Clinical Trial and Manufacturing Activities Fee and a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S., Bayer's milestone and royalty payment obligations are based on annual net sales of Ovaprene. Successful commercialization of a contraceptive product is subject to many risks and uncertainties, including factors outside of our control or Bayer's. We may never

receive the full amount of potential milestone payments under the agreement, and royalty and sublicense payments, if any, may be far less than projected. Failure to realize significant value under our license agreement with Bayer could have a material adverse effect on our business, results of operations and financial condition.

Our ability to raise capital may be limited by laws and regulations.

In 2020 and through March 29, 2021, we raised approximately $23.5 million in gross proceeds through the sale of equity securities under a Form S-3 “shelf” registration statement. Using a shelf registration statement 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 this registration statement was in the past, and may again be in the future, 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, in fiscal year 2020, we were subject to the "baby shelf rule" because the market value of our outstanding shares of common stock held by non-affiliates, or public float, was less than $75.0 million at the time we filed our shelf registration statement on Form S-3 and remained below $75.0 million during the year. This means that we were able to 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, any intended sale did 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 alternative to increase the cost 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 Our Securities-There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market,” 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.

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.

In addition, although a public offering under Nasdaq rules is not subject to the 20% limitation described above, it may involve publicly announcing the proposed transaction before it is completed, which often has the effect of depressing a company's stock price. Accordingly, our existing investors may suffer greater dilution if we seek to raise additional capital through such a public offering of our securities.

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 technical 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 our key portfolio candidates and any future candidates we may choose to develop. Due to our limited resources, we may be required to curtail clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates, or product candidates that we may in the future choose to develop, through the regulatory and development processes. 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 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 Clinical Development, Manufacturing and Commercialization– Delays in the commencement or completion of clinical testing of product candidates we are developing or may develop in the future 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.

We are heavily reliant on our ability to raise capital through capital market transactions. A low trading volume, price and market capitalization together with our lack of revenue, net losses and limited operating history may make it difficult and expensive for us to raise additional capital.

We are heavily reliant on our ability to raise additional capital by selling shares of our common stock or securities linked to our common stock. Our ability to raise capital through capital market transactions 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 continue to satisfy the listing requirements of the Nasdaq Capital Market, unfavorable market conditions or other market factors outside of our control, and the risk factors described elsewhere in this report, including those related to warrants we issued in February 2018. See "Our ability to raise capital may be limited by laws and regulations," above, and the risk factors under "-Risks Related to Our Securities," below. Even if we are able to raise additional capital, it will likely be dilutive to existing stockholders and the cost of such capital may be substantial and may be more expensive than the cost of capital for larger public companies. The terms of any funding we obtain may not be favorable to us and may be highly dilutive to our stockholders, and debt financing, if available, may involve restrictive covenants, operational restrictions and security interests in our assets that may have negative consequences for us, including, among other things, by increasing our vulnerability to adverse economic and industry conditions, limiting our ability to obtain additional funding and enter into partnership and other strategic agreements, and requiring the dedication of a portion of our cash flow to service our indebtedness. There can be no assurance that we can raise additional capital when needed. Failing to raise additional capital when needed would have a material adverse effect on our business.

We intend to seek collaborations with partners to develop and commercialize our product candidates and, if we enter into such collaborations, we may not have control over several key elements relating to the development and commercialization of our product candidates.

A key aspect of our strategy is to seek collaborations with partners, such as large 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 face significant competition in seeking these types of partners. Collaborations can be complex and time-consuming arrangements to negotiate and document. In 2020, we entered into a license agreement with Bayer for the commercialization of Ovaprene in the U.S., if it is approved, as well as agreements with contract research organizations Health Decisions, Inc. and Avomeen to help accelerate development of key programs in a capital-efficient manner. We may not be able to enter into other collaborations on acceptable terms, or at all.

We have no internal sales, marketing or distribution capabilities and our model is to partner with companies with existing sales and marketing capabilities to sell and distribute our products, if approved. If we fail to secure third-party collaborators for commercialization of our product candidates on a timely basis, even if they receive regulatory approval on our anticipated timelines, the commercial launch of our products may be significantly delayed, which could have a material adverse effect on our financial condition and results of operations. If we enter into definitive agreements with third parties to commercialize our product candidates, if approved, our revenues from the sale of such products will depend, in whole or in part, on the ability of such third parties to successfully market, sell and distribute our products and to perform their contractual obligations to us and there is no assurance these third parties will be effective or successful. In addition, if a partnered product is viewed by other potential collaborators as underperforming after commercial launch, our ability to partner other product candidates we are developing may be negatively impacted.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise and we may agree that the partner will control elements of product development and commercialization that are important to the product's success. Even if we are successful in entering into a strategic collaboration for one of our product candidates, our partner may fail to develop or effectively commercialize the product candidate because that partner:

- does not have sufficient resources or decides not to devote adequate resources to our collaboration due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- changes its business strategy and areas of focus;
- determines that the market opportunity is not attractive;
- cannot obtain sufficient quantities of our products or product candidates at a reasonable cost; or
- elects to terminate our strategic collaboration for any reason.

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, other potential sources of market exclusivity for such product, and industry and market conditions generally. The collaborator may also consider alternative products or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our products or product candidates.

We also 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.

Any potential collaboration agreement into which we might enter may call for licensing or cross-licensing of potentially blocking patents, know-how or other intellectual property. Due to the potential overlap of data, know-how and intellectual property rights, there can be no assurance that a collaborator will not dispute its right to use, license or distribute such data, know-how or other intellectual property rights, and this may lead to disputes, liability or termination of the collaboration.

If we elect to fund development or commercialization activities on our own or to co-promote a product with a third party, we will need to obtain significant additional capital, which may not be available to us when needed on acceptable terms or at all. If we elect to commercialize a product on our own or to co-promote a product with a third party, we may also need to rapidly grow and reorganize our company and develop and implement new systems and processes to support marketing, sale and distribution of the product, none of which we currently have in place as a clinical-stage biopharmaceutical company.

If we are not successful in attracting collaborators and entering into collaborations on acceptable terms for our product candidates or otherwise monetizing our product candidates, we may not complete development of or obtain regulatory approval for such 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.

The product candidates we are developing or may develop are likely to face significant competition and our business and operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is intensely competitive and characterized by rapid technological developments. Our competitors and potential competitors include large, well-established pharmaceutical and biotechnology companies, many of which have robust product portfolios and strong franchises in women's health. These companies include Merck & Co., Inc. (and its intended spinoff, Organon & Co.), AMAG, Inc., TherapeuticsMD, Inc., Cooper Surgical, Inc., AbbVie, Inc., Bayer AG, Johnson & Johnson, and Pfizer Inc. Additionally, several generic manufacturers currently market and continue to introduce new contraceptive and other products in women's health, including Sandoz International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., Mylan, Inc.,

Perrigo Company, PLC and Amneal Pharmaceuticals LLC. Many of our competitors or potential competitors, either alone or with strategic partners, 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 products; and
- approved products or product candidates in late stages of development for one or more of our target indications.

We will face intense competition from products that have already been approved and accepted by the medical community for contraception and the treatment of some of the conditions for which we are developing or may develop product candidates. If our product candidates fail to generate compelling clinical results or if patients and physicians fail to appreciate the convenience that our product candidates may offer, our commercial opportunity could be reduced or eliminated. We also expect to face competition from new products that enter the market. We believe there are a significant number of products currently under development intended to prevent pregnancy or to treat the same conditions for which our product candidates are in development. These competitive product candidates may prove safer, more tolerable and more effective and may be less expensive, 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 potential application of our product candidates noncompetitive or obsolete, even prior to completion of their development.

Our ability to compete effectively will be impacted by the efficacy and safety outcomes of our clinical trials, the label claims that the FDA or other regulatory authorities approve for our product candidates, the degree of acceptance of products we develop among the medical community and patients, and their preference for those products over available alternative products. It is possible that the potential advantages of our product candidates do not materialize. Our competitors may also obtain FDA or other regulatory approval for their competing products more rapidly than we may obtain approval for any of our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

See also the discussion of risks and uncertainties related to commercial success of specific product candidates we are developing under “Risks Related to Clinical Development, Manufacturing and Commercialization” below.

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

As of March 29, 2021, we had 23 employees, of which 16 were full-time and seven were part-time. Our focus on limiting cash utilization requires us to manage and operate our business in a highly efficient manner, relying on external consultants for needed product development and operational expertise, and to limit full-time personnel resources. With a small number of employees, our ability to supervise the external consultants and vendors we engage 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 response to the COVID-19 pandemic, in March 2020, we implemented work-from-home and restricted travel policies. Since March 2020, the governors of California and Massachusetts, states in which we have operations, have issued, rescinded and reinstated statewide or regional stay-at-home orders to help combat the spread of COVID-19 that have impacted our ability to require or allow our employees to work in our facilities. In addition, many, if not all, of our consultants, partners and vendors on which we rely heavily have implemented similar policies, are or may be subject to similar orders, and/or may re-allocate resources otherwise intended for our activities to activities intended to address the COVID-19 pandemic. While we have modified, and we may further modify, our work-from-home and restricted travel policies to allow some of our personnel to return to working in our facilities for a portion of their working time as the pandemic and state and local stay-at-home orders evolve, the duration of these policies and the extent and duration of various state and local stay-at-home orders currently is indeterminable. We have systems and technologies in place that enable our employees to work from home; however, state and local stay-at-home orders, work-from-home policies and travel restrictions may adversely affect our ability to effectively manage and operate our business, materially increase our expenses and may result in delays in our anticipated development program timelines.

In addition, we and our consultants, partners and vendors may experience high rates of employee leave during the COVID-19 pandemic due to increased rates of worker or family member illness, school and childcare center closures and federal and state family and medical leave laws that may allow workers to take up to 12 weeks of job-protected leave if unable to work or telework due to their own health condition or need to care for children or other

family members. Due to our small workforce, extended employee leaves of absence may adversely affect our ability to effectively manage and operate our business, materially increase our expenses, including by requiring us to hire new employees or engage additional consultants to perform the job responsibilities of the employees on leave, and may result in 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 pharmaceutical, biotechnology and medical device industries 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 employees could impede, delay or prevent the development and commercialization of our product candidates, hurt 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 employees, 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 and biotechnology 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. As a result, we may have to expend significant financial resources in our employee recruitment and retention efforts. Many of the other companies within the women’s health products industry 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 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.

Our business development strategy has included, and will likely continue to include, strategic transactions to assemble the portfolio of product candidates we develop. We may not successfully manage the integration of new assets or businesses, and the costs of these transactions may not be outweighed by the benefits we realize from them.

We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense. We assembled our current portfolio of product candidates through the acquisition of companies and assets and licensing transactions beginning in 2017. We expect to expand our portfolio from time to time through similar transactions. These transactions could subject us to several risks, including, but not limited to:

- our inability to appropriately evaluate the potential risks and uncertainties associated with a transaction;
- our inability to effectively integrate a new technology, product and/or business, personnel, intellectual property or business relationships; and
- our inability to generate milestones or revenues from a strategic transaction sufficient to meet our objectives in undertaking the transaction.

If we underestimate development costs, timelines, regulatory approval challenges and commercial market opportunity for a strategic transaction, we may fail to realize the anticipated value of the transaction. Any strategic transaction we may pursue may not produce the outcomes and benefits we originally anticipated, may result in costs that outweigh the benefits, and may adversely impact our financial condition and be detrimental to our company in general.

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

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including

deliberate attacks, the deployment of harmful malware or ransomware, denial of service, and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and those of our third-party service providers, and could compromise the confidentiality, availability and integrity of our data, confidential information, or other intellectual property, all of which are vital to our operations and business strategy. Organizations and governmental bodies with far greater resources than ours dedicated to cyber security have proven vulnerable to cyber-attacks. There can be no assurance we will succeed in preventing cyber security breaches or successfully mitigate their effects.

Despite implementing security measures, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failure. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For example, losing clinical study data from future clinical studies could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. In addition, a security breach or privacy violation that leads to disclosure of personally identifiable information or protected health information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and subject us to litigation or other liability under laws and regulations that protect personal data. 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, and the further development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

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

We may become exposed to the risk of employees, independent contractors, clinical investigators, consultants, suppliers, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, clinical investigators, consultants, suppliers, commercial partners and vendors 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 law, or (4) comply with SEC rules and regulations. In particular, 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, independent contractors, clinical investigators, consultants, suppliers, commercial partners and 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 employees, independent contractors, clinical investigators, consultants, suppliers, commercial partners and vendors, 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 our reputation.

We expect to continue to incur increased costs as a result of operating as a public company, and our management will have to devote substantial time to compliance initiatives and corporate governance practices.

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. Under recently adopted SEC rules, 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 requirements of being a public company. Even while we have non-accelerated filer status, our management and other personnel will need to continue to devote

substantial time towards maintaining compliance with the requirements of being a public company. The Sarbanes-Oxley Act of 2002 and rules and regulations subsequently implemented by the SEC and Nasdaq imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel, of whom we have a small number, devote substantial time to these compliance initiatives. Moreover, if and when we become an accelerated filer, our compliance costs will increase.

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.

Risks Related to Clinical Development, Manufacturing and Commercialization

We depend heavily on the success of our lead product candidates, DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%. 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 any of these product candidates would likely adversely affect our business.

Our business depends on the successful clinical development and regulatory approval of 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 DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%, there is no guarantee of successful outcomes in future clinical studies of these product candidates or of obtaining marketing approval for any of them. The fact that the active pharmaceutical ingredients in certain of our product candidates, including DARE-BV1 and Sildenafil Cream, 3.6%, have received regulatory approval in other formulations and/or for other indications does not guarantee successful development of our product candidates. Clinical trials may never demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates.

We have never received a regulatory approval for any product. Even if we can conduct and complete clinical trials for these product candidates, we may not obtain regulatory approval to market and sell any of them, which would have a material adverse effect on our business and operations.

The loss or impairment of our rights under any license agreement for our lead product candidates could prevent us from developing or commercializing them, which would have a material adverse effect on our business prospects, operations and viability.

Our rights to some of our product candidates, including our lead product candidates, arise from license agreements with third parties. The loss or impairment of our licensed rights to develop and commercialize these product candidates, including as a result of our inability or other failure 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 company's prospects.

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, including a milestone payment due upon the FDA's approval to commence a pivotal human clinical trial of Ovaprene. See ITEM 1. "BUSINESS-Overview-License Agreements-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, 3.6% for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of the female sexual arousal disorder 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-Overview-License Agreements-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-OAB1. 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 specific 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-Overview-License Agreements-Catalent JNP License Agreement," above.

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 DARE-BV1 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. MilanaPharm may terminate our license 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-Overview-License Agreements-Hammock/MilanaPharm Assignment and License Agreement," above.

If any of our agreements with ADVA-Tec, SST, Catalent, or Hammock Pharmaceuticals/MilanaPharm are terminated, impaired, or limited, we could lose the ability to develop and commercialize Ovaprene, Sildenafil Cream, 3.6%, DARE-BV1, or any of our IVR product candidates, including DARE-HRT1, as applicable. The termination of our rights under these agreements to develop and commercialize any of our lead product candidates could have a material adverse effect on our business prospects and operations.

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 these candidates will ever be advanced successfully through clinical development.

Delays in the commencement or completion of clinical testing of product candidates we are developing or may develop in the future 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.

The tests and clinical trials of product candidates we develop may not commence, progress or be completed as expected, and 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 testing of 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 for commencement, completion of enrollment, and/or availability of results from our clinical studies, but those statements are predictions based on a number of significant assumptions and the actual timing of achievement of development milestones may differ materially from our predictions for a variety of reasons.

We currently do not have adequate capital to conduct all of the clinical studies that we plan to conduct in 2021 and 2022. Commencement of planned clinical studies may be delayed if we do not secure adequate capital. In addition to lack of adequate capital, commencement and/or completion of these studies may be delayed, terminated or suspended as a result of the occurrence of any of a number of other factors, including the need to obtain authorizations from the FDA and the institutional review boards, or IRBs, of prospective clinical study sites, delayed or inadequate supply of our product candidates or other clinical trial material, slower than expected rates of patient recruitment or enrollment, other factors described below, and unforeseen events. In addition, among other factors, our

ability to commence our planned pivotal clinical study of Ovaprene is subject to the FDA's review and clearance of an IDE.

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

- obtaining required funding;
- obtaining guidance or authorizations from the FDA or foreign regulatory authorities;
- finalizing the trial design as a result of discussions with the FDA, other regulatory authorities or prospective clinical trial investigators or sites;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining sufficient quantities of our product candidates and other clinical trial material; or
- obtaining IRB approval to conduct a clinical trial at a prospective site.

In addition, once a clinical trial has begun, it may experience unanticipated delays or be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to several factors, all of which could impact our ability to complete our clinical trials in a timely and cost-efficient manner, including:

- lack of adequate funding;
- failure to conduct the clinical trial in accordance with regulatory or IRB requirements;
- slower than expected rates of participant recruitment and enrollment;
- higher than anticipated participant drop-out rates;
- failure of clinical trial participants to use the 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 side effects or other adverse events related to the investigational treatment;
- delayed or insufficient supply of clinical trial material or inadequate quality of such materials;
- failure of our CROs or other third-party contractors to meet their contractual obligations to us in a timely manner, or at all; or
- delays quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

The COVID-19 pandemic remains a rapidly evolving and uncertain additional risk to our timelines for commencement and completion of our clinical trials. Our prospective or contracted clinical trial sites may temporarily suspend activities at their sites to help secure the safety of their employees or to adhere to government recommendations or orders related to social distancing and limiting public gatherings, or they may experience resource constraints stemming from the pandemic 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 clinical trials that we are able to initiate, we may experience lower than anticipated subject enrollment and completion rates, including because individuals may avoid medical settings due to concerns related to the pandemic or they may become subject to governmental orders or recommendations that impose curfews or that ask individuals to leave their homes only if essential. In addition, increased rates of worker illness and implementation of work-from-home and restricted travel policies due to the COVID-19 pandemic may delay any regulatory authority and/or IRB approvals necessary for our clinical trials and/or prevent our CROs and other third-party contractors who are necessary for the conduct of our clinical trials from meeting their contractual obligations to us in a timely manner, any of which could delay commencement and completion of our clinical trials.

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 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.

We plan to submit an NDA to the FDA for approval of DARE-BV1 based largely on data from our recently completed Phase 3 DARE-BVFREE clinical trial; however, there can be no assurance that the FDA will grant

marketing approval of DARE-BV1 for the treatment of bacterial vaginosis without additional clinical or nonclinical studies.

DARE-BV1 is a novel thermosetting bioadhesive hydrogel formulation of clindamycin, an antibiotic with FDA approval in other formulations to treat bacterial infections, including bacterial vaginosis. Bacterial vaginosis effects over 20 million women and is known for being a difficult vaginal infection to cure. Our formulation is designed to provide extended release of the drug at the site of infection over multiple days and require no intervention by the patient beyond the initial application, which we believe will improve outcomes. Other pharmaceutical companies have employed a similar approach, with clindamycin and other antibiotics, and have generated only marginally improved outcomes. DARE-BV1 has been studied in 30 women diagnosed with bacterial vaginosis in an investigator-sponsored study and in a randomized, multicenter, double-blind, placebo controlled Phase 3 clinical study that randomized 307 women diagnosed with bacterial vaginosis in 32 study sites across the U.S. In December 2020, we announced positive topline results from the Phase 3 DARE-BVFREE study. DARE-BV1 met the primary endpoint of the study and all of the pre-specified secondary efficacy endpoints, demonstrating significantly greater clinical cure rates compared to placebo.

Drug product candidates must demonstrate substantial evidence of effectiveness, as well as safety, to be approved in the U.S. The FDA has interpreted that statutory standard as generally requiring at least two adequate and well-controlled clinical trials, each convincing on its own, to establish effectiveness. Under certain circumstances the FDA will determine that data from one adequate and well-controlled clinical trial together with confirmatory evidence obtained prior to or after such clinical trial are sufficient to constitute substantial evidence of effectiveness. Based on discussions with the FDA regarding the DARE-BV1 program and, specifically, the DARE-BVFREE study design, we believe that data from the DARE-BVFREE study, together with other existing safety and efficacy data on DARE-BV1 and clindamycin, will be sufficient to demonstrate substantial evidence of effectiveness, as well as safety, of DARE-BV1; provided that, after a comprehensive review of data from the DARE-BVFREE study, complete results are at least as positive as the topline results. However, regardless of our analyses of and conclusions about the DARE-BVFREE study data, the FDA may determine that the data are not sufficiently robust or convincing and may require additional clinical and/or nonclinical studies prior to approval of DARE-BV1 to treat bacterial vaginosis. If additional unplanned development studies or other activities are required for regulatory approval, our R&D expenses and DARE-BV1's development timeline could increase significantly, DARE-BV1's value could decrease significantly, and our financial condition and results of operations could be materially adversely affected.

If DARE-BV1 receives FDA approval, it will face significant competition from existing and potentially new therapies. See "The commercial success of DARE-BV1 will depend on its effectiveness in treating bacterial vaginosis compared to available competitive products and on women's preferences" below.

Ovaprene is a drug/device combination and the process for obtaining regulatory approval in the United States will require compliance with more complex requirements of the FDA applicable to combination products. A change in the FDA's prior determination that Ovaprene has a device-primary mode of action and re-assignment of primary oversight responsibility to CDER would adversely impact Ovaprene's development timeline and significantly raise our costs to complete clinical development and obtain regulatory approval for Ovaprene.

Ovaprene is composed of both device and drug components and is considered a combination product by the FDA. It is an intravaginal contraceptive product that releases a locally acting spermiostatic agent and has a permeable knitted polymer in its center designed to create a partial barrier to sperm. The barrier seeks to block the progression of sperm into the cervical mucus while the agents seek to create an environment inhospitable to sperm. Ovaprene previously underwent a request for designation, or RFD, process with the FDA that determined that the product had a device-primary mode of action and CDRH would lead the review of a PMA for the product. If the designation were to be changed to drug-primary mode of action and assigned to CDER, or if either division 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 planned contraceptive effectiveness and safety 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. See also "The commercial success of Ovaprene will depend on market acceptance of a monthly, hormone-free intravaginal product, availability and effectiveness of alternative contraceptive products and women's preferences, as well as the success of Bayer's marketing and sales efforts" below.

The factors contributing to female sexual dysfunction disorders, including genital arousal disorders, are complex making the design and implementation of a successful clinical trial of Sildenafil Cream, 3.6% challenging.

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, clinical studies to evaluate effectiveness in any subset of the condition under the umbrella of Sexual Dysfunction, such as female sexual arousal disorder, or FSAD, are complex. Sildenafil Cream, 3.6% is designed to work primarily by increasing blood flow to the genital tissue. Therefore, it will be critical for us to identify and enroll patients in our clinical trials of Sildenafil Cream, 3.6% for whom inadequate blood flow to the genital tissue is the primary contributor to their arousal disorder. If we fail to screen properly, and instead enroll patients with different contributing factors, the results of our clinical trials are unlikely to demonstrate effectiveness of Sildenafil Cream, 3.6%. Even if we can identify women for whom inadequate blood flow to the genital tissue is the primary contributing factor to their sexual arousal difficulties, there is no guaranty that the use of Sildenafil Cream, 3.6% will improve their general feelings of arousal or that we can utilize a patient reported outcome measure that adequately captures their genital arousal response. Given the factors contributing to arousal disorders, we may be required to run clinical trials in large patient populations, extending the timeline and increasing the cost of development for Sildenafil Cream, 3.6%.

Today, there are no FDA-approved treatments for FSAD, and we lack a precedent program to assist in the design of our clinical trials. These factors increase our development risk and the chance of failure. While we have worked with experts to develop novel patient reported outcome, or PRO, instruments for our planned Phase 2b study of Sildenafil Cream, 3.6%, tested the proposed 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, the Phase 2b study may nevertheless fail to demonstrate effectiveness of Sildenafil Cream, 3.6% in treating FSAD. Our failure to design and implement a successful clinical trial for Sildenafil Cream, 3.6% could have materially adverse effect on our business and our financial condition.

DARE-HRT1 and DARE-FRT1 utilize a vaginal ring technology that has not completed any human clinical trials.

DARE-HRT1 represents the earliest of our clinical-stage assets and the Phase 1 study in Australia represents the first human testing of this novel intravaginal ring technology. DARE-FRT1 utilizes the same IVR technology as DARE-HRT1. Other than the Phase 1 study of DARE-HRT, to date, all studies of DARE-HRT1 and DARE-FRT1 have been in vitro studies or animal studies. The risks associated with earlier stage technologies tend to be higher and the rate of failure tends to be greater. While the IVR technology has generated promising results in pre-clinical studies, there can be no assurance these results will be replicated when tested in human subjects. Even if successful, many approved therapies exist for treating symptoms of menopause, including vasomotor symptoms, and for pregnancy maintenance. There is no guaranty that women will prefer the convenience of a monthly vaginal ring over pills, patches and creams. Failure of DARE-HRT1 in the ongoing Phase 1 clinical study could have a meaningful adverse effect, not only on the DARE-HRT1 program, but also on the DARE-FRT1 program and the likelihood of the IVR technology being investigated for use in another indication. These developments would materially impact the value of this technology platform to our stockholders.

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.

Our business model relies on the outsourcing of important product development functions, tests and services to CROs, medical institutions and other specialist providers, vendors and consultants. We rely on these third parties to conduct our clinical trials and perform related activities, including quality assurance, clinical monitoring and clinical data management, as well as to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals for our product candidates. For example, we engaged CROs to run all aspects of the PCT clinical trial for Ovaprene and the Phase 3 clinical trial of DARE-BV1. We similarly expect to rely on CROs and other third parties to perform all clinical and nonclinical testing and many other important development and regulatory affairs activities needed to support applications for regulatory approvals of all product candidates we develop. We do not control these third parties and they may not devote sufficient time and resources to our projects, or their performance may be substandard, resulting in clinical trial delays or suspensions or delays in submission of our marketing applications or failure of a regulatory authority to accept our applications for filing. There is no assurance that the third parties we engage will be able to provide the functions, tests or services as agreed upon, including the agreed upon price and timeline, or to our requisite quality standards, including due to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic. We rely on the efforts of these third

parties and if they fail to perform as expected, we could suffer significant delays in, and potentially failure of, the development of one or more of our product candidates.

There is also no assurance these third parties will not make errors in the design, management or retention of our data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, regulatory approval of current and future product candidates, may be delayed, prevented or cost significantly more than expected, all of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on third-party suppliers and manufacturers of our product candidates, including multiple single source suppliers and manufacturers and, if approved, we expect to continue to rely on third parties for the manufacture of our products and supply of their component substances and materials.

Our product candidates and, if approved, our products (including their respective components) must be manufactured, packaged, tested, and labeled in conformity with cGMP and other applicable regulatory requirements. We have a small number of employees and no personnel dedicated to marketing, manufacturing or sales and distribution. We 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. If we receive the requisite regulatory approvals for one or more products, we expect to rely on third parties for commercial manufacture such products, and as such we will be subject to inherent uncertainties related to product safety, availability and security. In some cases, we may be contractually required to obtain supplies of our product candidates and approved products, if any, from specific third parties. For example, our agreement with ADVA-Tec limits our ability to engage a manufacturing source for Ovaprene other than ADVA-Tec during its development period as well as following regulatory approval. If ADVA-Tec fails to produce sufficient clinical supply of Ovaprene on anticipated timelines, our ability to complete clinical development and seek regulatory approval of Ovaprene could be significantly delayed. If Ovaprene receives marketing approval, failure by ADVA-Tec to produce sufficient quantities of the product to meet commercial demand could have a significant adverse effect on our income and ability to become profitable. To date, ADVA-Tec has only produced a small number of devices for clinical testing. Furthermore, for some of the key raw materials and components of Ovaprene, we have only a single source of supply, and alternate sources of supply may not be readily available.

Under the terms of the SST license agreement, SST will be responsible for obtaining supplies of Sildenafil Cream, 3.6% for the Phase 2 clinical trials expected to be conducted in the United States. Thereafter, we will be responsible for obtaining pre-clinical, clinical and commercial supplies of Sildenafil Cream, 3.6%.

Under the terms of the license arrangements for our other clinical-stage candidates, DARE-BV1 and DARE-HRT1, we will be responsible for sourcing the supply of the active ingredients and arranging for the manufacture of the products. We do not yet have any agreements in place for commercial production of DARE-BV1. We currently plan to obtain commercial supply of DARE-BV1 from the CMO that manufactured DARE-BV1 clinical trial material for the DARE-BVFREE Phase 3 study. However, there can be no assurance that we will enter into any such agreement with that CMO in a timely manner, or at all. If we are unable to do so, we would be forced to seek to engage a new CMO to manufacture commercial supply of DARE-BV1, which could lead to delays in regulatory approval and commercial launch in the U.S., as well as higher manufacturing costs. In addition, future supplies of raw materials required to produce DARE-BV1 and Sildenafil Cream, 3.6% may be more difficult and costly to obtain. For example, our current supplier of clindamycin is located in China, and our current supplier of sildenafil is located in India. Should these suppliers slow production or shut down their factories due to the COVID-19 pandemic, or for any reason, we may not be able to obtain adequate supplies of clindamycin or sildenafil to satisfy our commercial or clinical development supply requirements. In addition, political relations between the U.S. and China could affect our ability to obtain adequate supply of clindamycin from our current supplier at reasonable costs. If these circumstances were to occur, we could be forced to source clindamycin or sildenafil from different suppliers, which could lead to higher costs and delays in clinical development, regulatory approval and commercial launch of DARE-BV1 and Sildenafil Cream, 3.6%.

Because we currently rely, and expect to continue to rely, on third parties to supply and manufacture our product candidates and their respective components (including the active pharmaceutical ingredients) and, if approved, our commercial products, we do not expect to control the manufacturing processes for their production, all of which must be made in accordance with relevant regulations, which include, among other things, quality control, quality assurance, compliance with cGMP and the maintenance of records and documentation. Continuous compliance with cGMP and other applicable requirements, requires significant expenditure of time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging,

quality control, recordkeeping and other requirements. In the future, it is possible that we or our third-party suppliers or manufacturers may fail to comply with cGMP requirements, other applicable FDA regulations, the requirements of other regulatory bodies or our own requirements, any of which could result in suspension or prevention of commercialization and/or manufacturing of our products or product candidates, delay or suspension of ongoing research, including clinical trials, disqualification of data or other enforcement actions such as product recall, injunctions, civil penalties or criminal prosecutions against us. Furthermore, we may be unable to replace any third-party supplier or manufacturer with an alternate supplier or manufacturer on a commercially reasonable or timely basis, or at all. If we are unable to obtain the product quantities needed for our clinical trials, and if approved, to meet commercial demand, our business will be materially adversely affected.

If we were to experience an unexpected loss of supply, or if any supplier or manufacturer were unable to meet its demand for our product candidates, including due to geopolitical actions, natural disasters or public health emergencies or pandemics, such as the COVID-19 pandemic, we could experience delays in research, planned or ongoing clinical trials or commercialization. We might not find alternative suppliers or manufacturers with FDA approval, of acceptable quality, or able to provide the appropriate volumes and at an acceptable cost. The long transition periods that may be necessary to switch manufacturers and suppliers would significantly delay our timelines, which would materially adversely affect our business, financial conditions, results of operations and prospects.

Third-party suppliers, manufacturers, distributors or regulatory service providers may not perform as agreed or may terminate their agreements with us, including due to the effects related to geopolitical actions, natural disasters, public health emergencies or pandemics, such as the COVID-19 pandemic, or force majeure events that affect their facilities or ability to perform. Any significant problem that our suppliers, manufacturers, distributors or regulatory service providers experience could delay or interrupt our supply of materials or product candidates until the supplier, manufacturer, distributor or regulatory service provider cures the problem, until the event that resulted in the delay or interruption is adequately addressed, or until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available, and we may not have recourse against the party who did not perform or terminated their agreement with us if such non-performance or termination is excused under our agreements with such party. Failure to obtain the needed quantities of our products would have a material and adverse effect on our business, financial condition, results from operations and prospects.

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 is 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 futility 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 extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to 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 actual 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. For example, while we reported

positive topline data for the Phase 3 DARE-BVFREE study of DARE-BV1, the FDA may nevertheless require additional efficacy or safety trials before it will accept a DARE-BV1 NDA for filing or approve the NDA.

Our business depends on obtaining the approval of regulatory authorities, and in particular, FDA approval, for our product candidates in a timely manner, and the requirements for obtaining approval may change over time, requiring more financial resources and development time than we currently anticipate.

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.

Our success depends on our ability to obtain regulatory approvals for our product candidates in a timely and cost-efficient manner. We have not submitted a marketing application or received approval to market any of our product candidates from any regulatory authority. Even if we successfully complete clinical studies, we may experience delays in our efforts to obtain marketing approvals for any of our product candidates. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction.

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, or following our review of outcomes of other similar product candidates under development. This could significantly lengthen our development timelines and cost. Further, the FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is 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 FDA on such data and other requirements. In addition, the announcement of new requirements by the FDA, the failure of a competitive product to receive regulatory approval, or the receipt of a CRL from the FDA by another company pursuing the FDA's 505(b)(2) pathway that may have implications for our proposed regulatory approval pathway could impact how investors and potential strategic parties view the development risks associated with our product candidates. Changing testing or manufacturing requirements for product candidates we develop 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.

If the FDA's Section 505(b)(2) pathway is not an available regulatory pathway for DARE-BV1, Sildenafil Cream, 3.6%, DARE-HRT1, DARE-FRT1, DARE-VVA1 and DARE-LARC1, as we currently expect, or for other product candidates we may develop in the future, the development of these product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than currently anticipated, and in any case may not be successful.

We intend to develop and seek approval for many of our product candidates, including DARE-BV1, Sildenafil Cream, 3.6%, DARE-HRT1, DARE-FRT1, DARE-VVA1, DARE-LARC1 and other candidates we may license or acquire, including ORB-204 and ORB-214, pursuant to the FDA's 505(b)(2) pathway. If the FDA determines that we may not use that pathway for the development of any of these candidates, then we would have to seek regulatory approval via a "full" or "stand-alone" NDA under Section 505(b)(1) of the FDCA. This would require us to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval including possibly pre-clinical data. If this were to occur, the time and financial resources required to obtain FDA approval for these candidates, and the complications and risks associated with the respective product candidate or candidates, would likely substantially increase and would have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. As described above, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies and information that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development programs for DARE-BV1, Sildenafil Cream, 3.6%, our IVR product candidates, including DARE-HRT1 and DARE-FRT1, DARE-VVA1, DARE-LARC1 ORB-204 and ORB-214.

Although the FDA's longstanding position has been that it may rely upon prior findings of safety or effectiveness to support approval of a 505(b)(2) application, this policy has been controversial and subject to challenge. In addition, notwithstanding the approval of an increasing number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and 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. 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.

Moreover, any delay resulting from our inability to pursue the FDA's 505(b)(2) pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the FDA's 505(b)(2) pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Even if we receive regulatory approvals for our product candidates, they may not gain acceptance among physicians, consumers or the medical community, thereby limiting our potential to generate revenue, which will undermine our growth prospects.

Even if our product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any new product by consumers, physicians, other health care professionals and third-party payors will depend on several factors, including:

- demonstrated evidence of efficacy and safety;
- sufficient third-party insurance coverage or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- the willingness of uninsured consumers to pay for the product;
- the willingness of pharmacy chains to stock the products;
- the prevalence and severity of any adverse side effects;
- availability of alternative products; and
- the convenience and comfort level to consumers provided by our product compared to alternative products.

If our products fail to provide a benefit over then currently available options, we are unlikely to generate sufficient revenues to achieve profitability.

The commercial success of DARE-BV1 will depend on its effectiveness in treating bacterial vaginosis compared to available competitive products and on women's preferences.

Today, there are many FDA-approved products for treating bacterial vaginosis, and many are generic. If approved, DARE-BV1 will compete with those products. Current therapies for the treatment of bacterial vaginosis primarily consist of oral and vaginal formulations of antibiotics delivered as a single dose or through multiple doses over consecutive days. Two of the most common antibiotics used today are generic clindamycin and metronidazole. In particular, DARE-BV1 will likely be compared with Clindesse® (clindamycin phosphate) Vaginal Cream, 2% as this treatment is a vaginally administered, single dose cream formulation of clindamycin. If physicians do not view the cure rates or continued clinical response rates that DARE-BV1 demonstrates in its clinical studies as significantly superior compared to other products available for the treatment of bacterial vaginosis, physicians may opt to continue to prescribe existing treatments rather than recommend or prescribe our product to their patients. In addition, women may prefer orally delivered options to our vaginally delivered product unless our product is viewed by them as providing significantly superior efficacy, safety and/or convenience.

Should DARE-BV1 receive marketing approval, its commercial success will depend on many factors:

- strength of the efficacy data supporting the cure and clinical cure rates;
- patient satisfaction and willingness to use it again and refer it to others;
- the success or failure of other branded therapies;
- preference by women for a vaginally administered therapy;
- price pressure given today's high level of generic treatments; and

- approval of new entrants, including alternative, non-antibiotic treatment options.

Additionally, if we are not successful in attracting an acceptable commercialization partner or entering into an agreement with acceptable terms on a timely basis or at all, commercial launch of DARE-BV1 could be significantly delayed. Further, any future commercialization collaboration may not be successful, in which case our ability to realize the full market potential of our product could be harmed.

Any of these factors could reduce the commercial potential for DARE-BV1 and place pressure on our business, financial condition, results of operation and prospects, particularly if DARE-BV1 is the first product candidate for which we receive regulatory approval.

The commercial success of Ovaprene will depend on market acceptance of a monthly, hormone-free intravaginal product, availability and effectiveness of alternative contraceptive products and women's preferences, as well as the success of Bayer's marketing and sales efforts.

Today, there are a variety of hormonal and non-hormonal contraceptive options available to women, including oral contraceptive pills and intrauterine devices, newer hormonal contraceptive products including implants, injectables, vaginal rings, patches, and hormonal intrauterine systems, and non-hormonal methods such as female condoms, novel diaphragms, and new methods of female sterilization. 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 have a typical use efficacy outcome (which is the expected rate of pregnancy protection once the product is used widely under everyday circumstances) comparable to current non-implanted hormonal contraceptive methods (pills, patches and vaginal rings), which is approximately 91% typical use efficacy. Clinical testing will also need to demonstrate that the device can be safely worn for multiple weeks.

If we receive regulatory approval to market Ovaprene, its commercial success, or the success of any other future contraceptive product candidate we may seek to develop, including our current pre-clinical candidates, will depend upon the contraceptive market and market acceptance of an alternative method. Risks related to market acceptance include:

- minimum acceptable contraceptive efficacy rates;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options;
- changes in health care laws and regulations, including the ACA, and its effect on pharmaceutical coverage, reimbursement and pricing, and the birth control mandate;
- competition from new lower dose hormonal contraceptives with more favorable side effect profiles; and
- new generic contraceptive options including a generic version of the hormone-containing intravaginal product NuvaRing®.

If one or more of these risks occur, it could reduce the market potential for Ovaprene, or any future contraceptive product we may seek to 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 is 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 Sildenafil Cream, 3.6% will depend on the availability of alternative products for female sexual dysfunction disorders and women's preferences, in addition to the market's acceptance of our topical cream.

Today, there are no FDA-approved products to treat FSAD. While our goal is for Sildenafil Cream, 3.6% to be the first product to receive such approval, one or more competitive products may be approved before our product. Even if we achieve our goal of being first-to-market for FSAD, the costs associated with introducing a new product into the sexual dysfunctions market would likely be significant, and regardless of the amount spent, there is no guarantee that our new product will be broadly adopted. Women may be hesitant to use Sildenafil Cream, 3.6% for many reasons, including the lack of experience with any product designed to treat FSAD, the lack or perceived lack of clinical evidence supporting its benefits, and the out-of-pocket cost of Sildenafil Cream, 3.6%, particularly if it is not covered by insurance.

Our commercial success with Sildenafil Cream, 3.6% will depend, in large part, on the ability of the product candidate to demonstrate safety and effectiveness in treating FSAD in clinical trials, as well as our ability to educate doctors and women about the need to diagnose and treat FSAD and the potential benefits of using of Sildenafil Cream, 3.6%, at which we or any third party with which we may collaborate to commercialize Sildenafil Cream, 3.6% may not prove successful. Sexual arousal can be influenced by many emotional and physiological factors. To be successful, our clinical trials of Sildenafil Cream, 3.6% must anticipate such factors. Sildenafil Cream, 3.6% is designed to increase local blood flow to the genital tissue. Even if Sildenafil Cream, 3.6% demonstrates success in increasing blood flow, the product candidate may not demonstrate a significant, or any, increase in arousal or improvement in the overall sexual experience in some women in our clinical trials. If we fail to generate compelling clinical results, we may not receive regulatory approval to market Sildenafil Cream, 3.6%, or, if approved, many physicians may not prescribe and/or many women diagnosed with sexual arousal disorder may opt not to try Sildenafil Cream, 3.6%. If we fail to produce strong clinical outcomes, our ability to build a commercial market for Sildenafil Cream, 3.6% will be materially adversely impacted.

The commercial success of DARE-HRT1 will depend on the availability of alternative products for managing the vasomotor and vaginal symptoms of menopause and women's preferences, in addition to the market's acceptance of our IVR.

Treatments to address the symptoms associated with menopause, including the vasomotor symptoms, also known as hot flashes, include combinations of prescription hormones, some of which are FDA-approved and others which are prepared in compounding pharmacies. Numerous products already exist, and this number is likely to expand with time. In addition, there has been an emerging preference among some women and providers for bio-identical hormones that are chemically identical to those the body produces. DARE-HRT1 is designed to offer a convenient vaginal ring that continuously delivers a combination of bio-identical estradiol and progesterone over 28 days. Until relatively recently, no FDA-approved bio-identical hormone treatments existed. In 2018, Bijuva® estradiol and progesterone capsules, which are to be taken daily, received the first such approval. Studies have failed to demonstrate that bio-identical hormones are safer than other 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, if approved for hormone therapy, include:

- preference for a vaginal ring delivery of hormone therapy over pills, patches and creams by menopausal women;
- data regarding symptom relief of DARE-HRT1 over other hormonal treatments for vasomotor symptoms associated with menopause;
- preference for bio-identical hormones by women and health care providers; positive or negative news and research regarding bio-identicals;
- the success or failure of Bijuva®, the first FDA-approved bio-identical product;
- new information supportive or against the use of hormones in menopause; and
- availability of insurance reimbursement for DARE-HRT1.

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.

If we suffer negative publicity concerning the safety or efficacy of the product candidates we develop, our reputation could be harmed, and we may be forced to cease development of such products.

If concerns should arise about the actual or anticipated clinical outcomes regarding the safety of any of our product candidates, 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 our product candidates, which could lead to a decline in potential opportunities with strategic partners or collaborators as well as investors’ expectations for the product candidate’s or our company’s prospects and a decline in the price of our common stock.

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 DARE-BV1, Ovaprene, or Sildenafil Cream, 3.6% 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 would be materially harmed, and we could also be subject to potential claims and lawsuits.

Our Sildenafil Cream, 3.6% product candidate may pose a greater risk to older or elderly women.

FSAD is a condition that impacts women of many ages, including older and elderly populations. Sildenafil, the active ingredient in Sildenafil Cream, 3.6%, 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, 3.6% and we have not yet thoroughly studied the topical or clinical pharmacology of this drug candidate in different patient populations. Should Sildenafil Cream, 3.6% show increased risk of adverse reactions, or signs thereof, in older or elderly women, the potential market for Sildenafil Cream, 3.6% could be significantly limited and our business prospects could be harmed.

If the product candidates we develop are associated with or cause serious adverse events or other undesirable side effects during clinical testing, we may be required to conduct clinical and nonclinical studies that currently are not part of our development plans, which may delay or prevent marketing approval, or, if approval is received, may require a product to be taken off the market, require product labeling to include safety warnings or result in implementation of other restrictions that could significantly decrease our product sales.

Serious adverse events or other undesirable side effects associated with or caused by any product candidate we develop, could arise during clinical development or, if approved, after product launch. Data from future clinical trials may show that a product candidate causes or may cause serious adverse events or other undesirable side effects, which could interrupt, delay, or cause the termination of clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities. If such serious adverse events or other undesirable side effects occur:

- during the clinical development phase, regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;
- during the commercial or post-marketing phase, regulatory authorities may require the addition of specific warnings or contraindications to product labeling or field alerts to physicians and pharmacies;
- we may have to change the way the product is administered or the labeling of the product;
- we may have to conduct additional clinical trials with more patients or over longer periods of time than anticipated;
- we may have to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may have to limit the patients who can receive the product;
- we may be subject to promotional and marketing limitations on the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take an approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or a commercial partner from achieving or maintaining market acceptance of product candidates we develop, or could substantially increase development and/or commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from product sales or receiving royalties and other payments based on sales by commercial partners.

The women's health market includes many generic products and the growth in generics is expected to continue, making the successful introduction of branded products for contraception, bacterial vaginosis and hormone therapy difficult and expensive.

The proportion of the U.S. market made up of generic products has been increasing. If this trend continues, it may be more difficult for us or a commercial partner to introduce a new branded product, if approved, 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 the areas in which two of our lead product candidates will compete, contraception and the treatment of bacterial vaginosis. In order for Ovaprene and DARE-BV-1 to develop commercial markets and for insurers to cover these higher cost products, they must demonstrate better patient compliance and clinical benefit in their clinical trials compared to other available products.

Additional marketing and educational efforts may be required to introduce a new branded prescription product in order to overcome the trend towards generics and gain access to reimbursement by payors. If we or a commercial partner cannot introduce a product, if approved, at our desired price or gain reimbursement from payors for an approved product, or if patients opt for a lower cost generic product rather than pay out-of-pocket or a higher co-pay for our product, our revenues or royalties and other license fees, as applicable, will be limited.

Changes in health care laws and regulations may eliminate current requirements that health insurance plans cover and reimburse FDA-cleared or approved contraceptive products without cost sharing, which could reduce demand for branded products and lead to a preference for generic options. If the out-of-pocket costs for Ovaprene or other contraceptive products we develop are deemed by women to be unaffordable, a commercial market may never develop.

If approved, we cannot be certain that third-party reimbursement will be available for Ovaprene, and even if reimbursement is available, the amount of any such reimbursement. The ACA and subsequent regulations enacted by the Department of Health and Human Services, or 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 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 products. These regulations have been, and may be further, modified, repealed, or otherwise invalidated, in whole or in part. For example, a challenge to the constitutionality of the ACA is currently pending at the Supreme Court, with a decision expected in spring 2021. If the ACA is declared invalid in its entirety, the requirement for health plans to cover women's preventive care without cost sharing would likely be eliminated. Even if the ACA is not repealed, the DHHS regulations to specifically enforce the preventive health coverage mandate were modified under the Trump Administration, which altered the mandate to allow certain employers and insurers to opt out of birth control coverage for religious or moral reasons, which was partially upheld by the Supreme Court in July 2020 but continues to be the subject of litigation and other challenges. We cannot predict the timing or impact of any future rulemaking, court decisions or other changes in the law, although the Biden Administration has signalled its intent to protect women's access to contraception and to ensure reproductive rights for women both domestically and abroad, such as with a Presidential Memorandum issued on January 28, 2021 that rescinded several policies that had been implemented during the Trump Administration.

Any repeal or elimination of the 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, such as Ovaprene, at all. As a result, we expect that our success will depend on the willingness of patients to pay out-of-pocket for Ovaprene in the event that either they do not have insurance or their insurance requires payment of a portion of Ovaprene by the patient, thus increasing the patient's overall cost to use Ovaprene. This could reduce market demand for Ovaprene or any other contraceptive candidates we may seek to develop, such as DARE-LARC1, ORB 204, ORB 214 and DARE-RH1, if and when they receive FDA approval, which would have a material adverse effect on our business, financial condition, and prospects.

As no FDA-approved treatments for FSAD currently exist, there is little precedent to help assess whether health insurance plans will cover Sildenafil Cream, 3.6% if approved.

There is no assurance that third-party reimbursement will be available for Sildenafil Cream, 3.6%, if it receives regulatory approval. 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, 3.6% to be a life-style 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,

3.6% 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, 3.6% 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, 3.6%, which would have a material adverse effect on our financial condition and prospects.

Even if we obtain regulatory approval in the United States or elsewhere to market any of our products, the commercial success of our products and our financial prospects will depend in part on the extent to which the costs of our products will be covered by third-party payors for prescription medical products.

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 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, or a commercial partner, to sell our products on a profitable basis. 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 products, including coding, coverage and payment. 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 our products could differ significantly from payor to payor. In the U.S., 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. Accordingly, 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.

To secure coverage and reimbursement for any product that might be approved for sale, we 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. 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. 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.

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 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 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. 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 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 indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful. It is uncertain whether and how future legislation or regulatory changes, to the ACA and otherwise, could affect prospects for 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 to generate revenue, attain profitability or commercialize our product candidates.

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

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 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 healthcare 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 healthcare 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 healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare 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 healthcare 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, certain other 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 transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that 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 possibly other persons, 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 healthcare professionals.

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

Although our compliance programs and those of commercial partners, 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 operations and arrangements with third parties comply with applicable healthcare 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 healthcare laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, 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, healthcare 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 healthcare 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 healthcare programs.

If regulatory authorities challenge our activities, or those of a commercial partner, 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 partner, regardless of the outcome, would be costly and time consuming, and may negatively affect our results of operations and financial condition.

We have no internal sales, marketing or distribution capabilities and our model is to partner with companies with existing sales, marketing and distribution capabilities to commercialize our product candidates, if approved. Any failure by such third parties could negatively impact our business and our ability to develop and market any approved products.

We currently do not intend to directly sell or distribute our products into the market and instead intend to enter into agreements with third parties to market, sell and distribute and provide related support services for any of our product candidates that receive regulatory approval. Failure to timely enter into such agreements could delay commercial launch of any such product. In addition, the terms of such agreements will impact the current and future value of such products to us, including the timing of any potential cash payments, including royalty and milestone payments. This reliance on third parties will also subject us to uncertainties related to these services, including the quality of such services. These third parties may not effectively market, sell or distribute our products. Further, we would depend on these third parties to ensure that the distribution process accords with applicable law and regulations, which include, among other things, compliance with current good documentation practices, the maintenance of records and documentation, and compliance with applicable state laws that govern the licensure of distributors of prescription medical products. Failure to comply with these requirements could result in significant remedial action, including improvement of facilities, suspension of distribution or recall of product. Furthermore, we

may be unable to replace any commercial partner or distributor with an alternate third party on a commercially reasonable or timely basis, or at all.

Additionally, any failure by us to forecast demand for a finished product, and failure by us to ensure our distributors and marketing partners have appropriate capacity to distribute and sell such quantities of finished product, could result in an interruption in the supply of certain products and a decline in sales of that product.

Should we decide to take a more active role in the commercial distribution of our products, such efforts would require the investment of significant capital, an expansion of our team and additional risk.

The commercial success of product candidates we develop will significantly depend on the label claims that the FDA and comparable regulatory authorities outside the United States approve for the product.

The commercial success of any of our product candidates will significantly depend upon our ability to obtain approval from the FDA and other regulatory authorities of product labeling containing adequate information regarding the product's expected features or benefits. Failure to achieve such approval will prevent or substantially limit our ability to advertise and promote such features and benefits in order to differentiate DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, DARE-HRT1, the other product candidates currently in our portfolio or any future product candidate from competing products. This failure would have a materially adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive marketing approval from the FDA for our product candidates, we may fail to receive similar approval outside the United States, which could substantially limit the value of such products.

To market any of the product candidates we are developing outside the United States, we 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 United States, 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 United States, and we may have to develop our own additional data to seek approvals in other jurisdictions. In addition, in many countries outside the United States, 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 United States may be different and inconsistent with the United States labeling requirements, negatively affecting our ability to market our products in countries outside the United States.

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 fail to comply with applicable foreign regulatory requirements. In such an event, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Many 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.

Our business may be adversely affected by unfavorable or unanticipated macroeconomic conditions.

Various macroeconomic factors could adversely affect our business, our results of operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty) or a global health emergency, and the current and future conditions in the global financial markets.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payers and distributors to purchase, pay for and effectively distribute our products, if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future third-party manufacturers, sole source or single source 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 could have a material adverse effect on our ability to develop and obtain regulatory approvals for our current and any future product candidates, and, if approved, market and sell our products or provide sufficient quantities of our products to meet market demand.

Risks Related to Our Intellectual Property

Our failure to adequately protect or enforce our and our licensors' intellectual property rights could materially harm our proprietary position in the marketplace or prevent or impede the commercialization of our current and potential future products.

Our success depends in part on our ability, and the ability of our licensors, to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technologies and products. The patents and patent applications relied upon by us are licensed to us by third parties. Our ability, or the ability of our licensors, to protect our product candidates from unauthorized use or infringement by third parties depends substantially on our abilities and the abilities of such licensors to obtain and maintain, or license, valid and enforceable patents. 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 United States Patent and Trademark Office, or 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 FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book"). 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 application (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.

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, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Our patent strategy for protecting DARE-BV1 includes in-licensing a patent family from TriLogic Pharma and MilanaPharm whose last claim expires in the fourth quarter of 2028 in the United States and Europe, with additional patent applications pending that could have terms into 2036. MilanaPharm has the first right to prepare, file, prosecute and maintain all such patents, at MilanaPharm's sole cost and expense. MilanaPharm and TriLogic must keep us informed regarding the preparation, filing, prosecution, and maintenance of the licensed patents, provide us with reasonable opportunity to review and comment on material communications to and from the applicable patent authorities and take all reasonable comments made by, and otherwise act in accordance with instructions provided by, us on matters related to prosecution, maintenance and enforcement related to the licensed patents. If MilanaPharm decides not to prepare, file, prosecute, or maintain any licensed patent, we have the option, in our sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such patent at our expense, and we may deduct some or all of such patent expenses from amounts payable to MilanaPharm under our license agreement.

Our patent strategy for protecting Ovaprene includes in-licensing a patent family from ADVA-Tec, whose last claim expires in August 2028, but which could be extended to August 2033 in the United States and Europe. Patent prosecution for the intellectual property incorporated into Ovaprene is entirely controlled by ADVA-Tec and we have little, if any, influence or control over such patent prosecution.

Our patent strategy for protecting Sildenafil Cream, 3.6% includes in-licensing a patent family from SST, whose last U.S. claim expires in June 2029, but which could be eligible for three-year market exclusivity under the Hatch-Waxman Act in the United States. However, if granted 3-year exclusivity, generic applicants can still submit an abbreviated application during the 3-year period and the FDA is required to review the application, but will defer any approval until the end of the 3-year period. Three-year exclusivity differs from 5-year exclusivity under the Hatch-Waxman Act, which bars the submission of a generic application during the 5-year period, with the exception that a generic application can be filed after 4 years if it contains a Paragraph IV certification challenging an Orange Book-listed patent for the brand drug.

With respect to patents related to Sildenafil Cream, 3.6%, SST has the sole right, but not the obligation, to prepare, file, prosecute and maintain such patents. We will be responsible for the costs incurred to maintain and prosecute all such patents and we will be kept informed of all strategies. However, we will have little if any, influence or control over implementing the patent strategy.

With respect to patent rights related to our IVR product candidates, including DARE-HRT1, The General Hospital Corporation (known as MGH) has the sole right to prosecute and maintain its patent rights, and we have the right to prosecute and maintain Catalent's patent rights. We will be responsible for the costs incurred by MGH to maintain and prosecute such patents and we will be kept informed of all strategies. However, we will have little, if any, influence or control over MGH's implementation of the patent strategy.

With respect to patents related to DARE-VVA1, we have the right and obligation, at our expense, to prosecute and maintain the in-licensed patent rights in certain major markets, if possible.

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 prosecution 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 United States 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 United States 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.

The patents and the patent applications covering Sildenafil Cream, 3.6% and DARE-BV1 are limited to specific formulations, processes and uses of sildenafil and clindamycin, and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors.

The active ingredient in our product candidate for FSAD, Sildenafil Cream, 3.6%, is sildenafil and the active ingredient in our product candidate for the treatment of bacterial vaginosis, DARE-BV1, is clindamycin. Patent protection for these ingredients has expired and generic products are available. As a result, a competitor that obtains the requisite regulatory approvals could offer products with the same active ingredient in a different formulation so long as the competitor does not infringe any process, use or formulation patents that we have developed, or that may not be barred by any three-year Waxman-Hatch Act exclusivity we might enjoy upon approval of our products.

Competitors may seek to develop and market competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for Sildenafil Cream, 3.6% and DARE-BV1 could be significantly harmed if competitors are able to develop and commercialize alternative formulations using these ingredients.

The patents and the patent applications covering our IVR product candidates cover the method of delivery and the device and our market opportunity may be limited by the lack of patent protection for the active ingredients themselves and other formulations, delivery technology and systems that may be developed by competitors.

The active ingredients in our IVR product candidates include bio-identical progesterone, estrogen and oxybutynin, and none of those ingredients are proprietary to us. As a result, we must compete with currently available products and any future products developed by competitors using same active ingredients in a different formulation or via a different delivery system. The commercial opportunity for our IVR product candidates, including DARE-HRT1 for hormone therapy, could be significantly harmed if competitors develop and commercialize alternative formulations or better delivery approaches.

The patents and the patent applications covering the use and delivery of DARE-VVA1 and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations, delivery technology and systems that may be developed by competitors.

The active ingredient in DARE-VVA1, tamoxifen, is not proprietary to us. As a result, we must compete with currently available products and any future products developed by competitors using the same active ingredient in a different formulation or via a different delivery system. The commercial opportunity for our product candidate for the

treatment of vulvar and vaginal atrophy could be significantly harmed if competitors develop and commercialize alternative formulations or better delivery approaches.

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. If we were unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

With respect to DARE-BV1, we have the initial right to enforce patents we license from TriLogic and MilanaPharm against third parties whose activities infringe such patents in a manner that could affect our exercise of the licenses granted to us, and TriLogic and MilanaPharm must reasonably cooperate with in any such suit, including, if necessary, by being joined as a party to any such suit. In some cases, MilanaPharm may assume the defense of a claim initiated by a third-party alleging infringement of a third party's intellectual property rights as a result of the manufacture or sale of a product we develop under our license agreement with TriLogic/MilanaPharm. While our license agreement would require MilanaPharm to indemnify us for certain losses arising from these third-party claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and sell DARE-BV1.

With respect to Ovaprene, ADVA-Tec has the right, in certain instances, to control the defense against any infringement litigation arising from the manufacture or development (but not the sale) of Ovaprene. While our license agreement with ADVA-Tec requires ADVA-Tec to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Ovaprene. Additionally, our license agreement with Bayer requires that we indemnify Bayer from and against all liabilities, damages, losses and expenses arising from or occurring as a result of development, manufacture, use or commercialization of Ovaprene by us or any licensee of ours, including without limitation, product liability claims, except in limited circumstances. As a result of our indemnification obligations to Bayer and limitations on ADVA-Tec's obligations to indemnify us, any patent infringement litigation relating to Ovaprene could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition.

With respect to Sildenafil Cream, 3.6%, we have the initial right to enforce the applicable licensed patents against infringers in the field of use where a third party is exploiting a topically applied pharmaceutical product that contains at least one of the same active pharmaceutical ingredients as a licensed product, and SST will provide us with reasonable assistance (excluding financial assistance), at our expense. We also have the initial right to defend any claim initiated by any third-party alleging that a licensed product developed or commercialized under the SST license agreement has infringed any third-party intellectual property rights. While the SST license agreement requires SST to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Sildenafil Cream, 3.6%.

With respect to our IVR product candidates, including DARE-HRT1, we have the first right to enforce the applicable licensed patents against third party infringers in the fields of pharmaceutical, therapeutic, preventative, diagnostic and palliative uses.

With respect to DARE-VVA1, we have the first right to enforce the applicable licensed patents against third-party infringers in all fields.

Our exclusive, in-license agreements covering the critical patents and related intellectual property related to our product candidates impose significant monetary obligations and other requirements that may adversely affect our ability to execute our business plan. The termination of any of these in-license agreements could prevent us from developing and commercializing our product candidates and may harm our business.

Our license agreements with Hammock/MilanaPharm, ADVA-Tec, SST and Catalent include intellectual property rights to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, and our IVR product candidates, including DARE-HRT1, respectively. These agreements, as well as our merger agreements with Pear Tree and Microchips, require us, as a condition to the maintenance of our license and other rights, and as merger consideration in the case of the agreement with Pear Tree, to make milestone and royalty payments and satisfy certain performance obligations. Our obligations under these in-license and merger agreements impose significant financial and logistical burdens upon our ability to carry out our business plan. Furthermore, if we do not meet such obligations in a timely manner, and, in the case of milestone payment requirements, if we were unable to obtain an extension of the deadlines for meeting such payment requirements, we could lose the rights to these proprietary technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Further, there is no assurance that the existing license agreements covering the rights related to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, and the IVR product candidates, or license agreements we enter into or acquire the rights to in the future, will not be terminated due to a material breach of the underlying agreements. With regard to the agreement covering Ovaprene, this would include a failure on our part to make milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities, or the loss of rights to the underlying intellectual property by any such licensors. With regard to the agreement covering Sildenafil Cream, 3.6%, this would include a failure to assume responsibility for suspended development activities within the requisite period, our failure to use commercially reasonable efforts in performing development activities, or the failure on our part to make milestone and royalty payments. With regards to the agreement covering DARE-BV1, this would include failure to use commercially reasonable efforts and resources 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, our failure to make milestone and royalty payments, or our failure to continue, or to resume, using commercially reasonable marketing efforts to sell a licensed product or process in a country after having launched such product or process in that country. With regard to the agreement covering our IVR product candidates, this would include a failure on our part to make milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities or the loss of rights to the underlying intellectual property by any such licensors. With regard to the merger agreement with Pear Tree, this would include our failure to use commercially reasonable efforts to bring a product to market.

Moreover, because some of our rights to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6% and the IVR product candidates are sublicensed pursuant to underlying agreements, there is no assurance that the existing license agreements covering the rights related to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, and DARE-HRT1 will not be terminated due to termination of the underlying agreements, or due to the loss of rights to the underlying intellectual property by Hammock's, ADVA-Tec's, SST's or Catalent's licensors. There is no assurance that we will be able to renew or renegotiate license agreements on acceptable terms if our license agreements with Hammock, ADVA-Tec, SST, TriLogic/MilanaPharm or Catalent, or the underlying agreements are terminated. 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 would materially and adversely affect our ability to develop and commercialize DARE-BV1, Ovaprene, Sildenafil Cream, 3.6% and our IVR product candidates, including DARE-HRT1.

We may also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, 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 third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. 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.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our 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, nondisclosure, and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, 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 or made known to the party by us during the course of the party's relationship with us. These agreements also 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 and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. We also have not entered into any non-compete agreements with any of our employees. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of future employment with any of our competitors. 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 in our market, which could materially adversely affect our business, operating results and financial condition.

Risks Related to Our Securities

The price of our common stock has been and may continue to be volatile and could subject us to securities litigation, including class-action lawsuits.

The stock market in general, and the market for biopharmaceutical companies in particular, have experienced volatility that has often been unrelated to the operating performance of particular companies. The stocks of small cap and microcap companies in the life sciences sector like ours tend to be highly volatile. We expect that the price of our common stock will be highly volatile for the next several years as we continue R&D and regulatory affairs activities necessary to obtain marketing approval for our product candidates, including pivotal clinical trials. The market price for our common stock may be influenced by many factors, including:

- failure or discontinuation of any of our research programs;
- actual or anticipated changes to our product development and approval timelines, results from any clinical trial, and communications or decisions from regulatory authorities relating to a review of or decisions on applications we submit for our product candidates, in each case particularly those related to our clinical-stage 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 unrestricted cash;
- the level of expenses related to development of product candidates we develop, and in particular our clinical-stage development programs;
- commencement or termination of any collaboration or licensing arrangement;
- the results of our efforts to discover, develop, acquire or in-license product candidates or products, if any;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies and effects from geopolitical actions, including war and terrorism, or natural disasters such as earthquakes, typhoons, floods and fires or public health emergencies or pandemics, such as the COVID-19 pandemic;
- regulatory or legal developments in the United States and other countries;

- changes in the structure of health care payment systems;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- recommendations or reports issued by securities research analysts;
- sales of common stock 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.

There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market.

Our common stock is listed on the Nasdaq Capital Market. To maintain our listing we are required to satisfy continued listing requirements, including the requirements commonly referred to as the minimum bid price rule and with either the stockholders’ equity rule or the market value of listed securities rule. The minimum bid price rule requires that the closing bid price of our common stock be at least $1.00 per share, and the stockholders’ equity rule requires that our stockholders' equity be at least $2.5 million, or, alternatively, that the market value of our listed securities be at least $35 million or that we have net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years. There can be no assurance we will continue to satisfy applicable continued listing requirements. For example, in 2018 and 2019, we were not in compliance with the minimum bid price rule and the stockholders' equity rule. We subsequently regained compliance with both rules, but there can be no assurance that we will continue to satisfy these or other continued listing standards and maintain the listing of our common stock with Nasdaq.

The suspension or delisting of our common stock, or the commencement of delisting proceedings, 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, or the commencement of delisting proceedings, 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.

Pre-clinical product candidates may not be valued 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 partners, 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. If DARE-LARC1, DARE-FRT1, DARE-VVA1, DARE-RH1 or the injectable etonogestrel product candidates we may license from Adare fail to be valued, our stock price may be adversely affected.

A significant portion of our total outstanding shares of common stock may be sold into the public market at any point, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, either by us or our stockholders. For example, since January 1, 2020 and through March 29, 2021, we sold an aggregate of 15.8 million shares of our common stock in at-the-market offerings. These sales, or the perception in the market that we or holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

As of December 31, 2020, there were 2.8 million shares of our common stock subject to outstanding options, almost all of which have been registered under the Securities Act on Form S-8. The shares so registered can be freely sold in the public market after being issued to the option holder upon exercise, 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. Furthermore, as of March 29, 2021, there were approximately 1.9 million shares of our common stock subject to outstanding warrants to purchase common stock, virtually all of which currently have an exercise price of $0.96 per share. To the extent these warrants are exercised, the shares underlying these warrants may be immediately sold in the public market.

The sale of our common stock in ATM offerings or under our Purchase Agreement 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.

During 2020, we relied on at the market, or ATM, offerings and sales of our common stock under our Purchase Agreement to fund a significant portion of our operations, and we may continue to use these facilities to fund our operations in the future. In March 2021, we gave notice to terminate the sales agreement pursuant to which we previously conducted ATM offerings, however, we are exploring entering into another sales agreement for ATM offerings. In April 2020, we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, pursuant to which Lincoln Park is obligated to purchase up to $15.0 million in shares of our common stock, at our sole discretion, subject to the terms and conditions set forth in the agreement and, as of March 29, 2021 approximately $3.0 million in shares remained available for us to sell under such agreement. We refer to this agreement as our "Purchase Agreement." The purchase price for the shares we may sell under our Purchase Agreement will vary based the market price of our common stock at the time we initiate a sale. Although we have the right to control whether we sell any shares, if at all, under these agreements, and we generally have the right to control the timing and amount of any such sales, we are, or may become, subject to certain restrictions, including those that limit the number of shares we may sell. For example, with respect to the Purchase Agreement, we may not sell more than 4,941,089 shares to Lincoln Park, which we refer to as the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price per share of all sales to Lincoln Park equals or exceeds $1.0117, and we may not sell shares to Lincoln Park if it would result in Lincoln Park beneficially owning more than 9.99% of our then outstanding shares of common stock. Accordingly, we may not be able to utilize the Purchase Agreement to raise additional capital when, or in the amounts, we desire. In addition, if our public float is below $75 million when we file our next annual report on Form 10-K, which will be due in March of 2022, we could become subject to the baby shelf rule and our ability to conduct primary offerings under a Form S-3 registration statement could become limited by the restriction that, during any 12-month period, we may not sell securities pursuant to General Instruction I.B.6 to Form S-3 having an aggregate market value of more than one-third of our public float, calculated in accordance with the instructions to Form S-3. To the extent we do sell shares of our common stock, 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 options and warrants may result in significant dilution to our stockholders.

As of December 31, 2020, we had outstanding options to purchase up to 2.8 million shares of our common stock and, and as of March 29, 2021, we had outstanding warrants to purchase up to approximately 1.9 million shares of our common stock. The exercise of a significant portion of our outstanding options and/or warrants may result in significant dilution to our stockholders.

The warrants issued in February 2018 contain price protection in the form of anti-dilution provisions that could harm trading in our shares and make it difficult for us to obtain additional financing.

The warrants we issued and sold in the underwritten public offering that closed in February 2018 (the "February 2018 Warrants") include price-based anti-dilution provisions. As of March 29, 2021, February 2018 Warrants to purchase up to approximately 1.9 million shares of our common stock were outstanding and the exercise price of those warrants was $0.96 per share. Under the terms of the February 2018 warrants, subject to certain limited exceptions, their exercise price will be reduced each time we issue or sell (or are deemed to issue or sell) any securities, including under the Purchase Agreement, for a consideration per share less than a price equal to the exercise price of the February 2018 Warrants in effect immediately prior to such issuance or sale (or deemed issuance or sale). If we issue shares of our common stock for cash, the consideration received therefor will be deemed to be the net amount of consideration we received therefor. In addition, if we issue, sell or enter into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of our common stock, the holders of the February 2018 Warrants will have the right to substitute such variable price for the exercise price of the February 2018 Warrants then in effect.

The overhang represented by the February 2018 warrants, coupled with the anti-dilution provisions of such warrants, may make it more difficult for us to raise additional capital, because of the possible substantial dilution to any new purchaser of our securities and the ability of holders of the warrants to enter into short sales of our stock. Any potential new purchaser of our securities may choose to value our common stock in such a manner that takes into

account the number of shares of our common stock that would be outstanding immediately following the exercise of all the outstanding February 2018 Warrants.

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

Our certificate of incorporation 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 are a smaller reporting company and a non-accelerated filer and the reduced disclosure requirements available to such companies 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 a 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, 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.

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 Second Amended and Restated By-Laws, as amended, 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 to amend or repeal certain provisions of the charter or bylaws.

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 Second Amended and Restated By-Laws, as amended, 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. 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. There is uncertainty as to whether a court (other than state courts in the State of Delaware, where the Supreme Court of the State of Delaware recently decided that exclusive forum provisions for causes of action arising under the Securities Act are facially valid under Delaware law) would enforce forum selection provisions and whether investors can waive compliance with the federal securities laws and the rules and regulations thereunder. 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, six 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 2. PROPERTIES

We lease real property to support our business. The office space for our corporate headquarters, which is in good operating condition, is in San Diego, California. We believe that the real property we lease meets our current needs and that we will be able to renew our lease when needed on acceptable terms or find alternative facilities.

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, and management is not aware of any contemplated proceeding by any governmental authority against us.

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 29, 2021, we had approximately 59 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. SELECTED FINANCIAL DATA

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

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 clinical-stage biopharmaceutical company committed to advancing innovative products for women’s health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. Our business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid to late-stage clinical development, and to establish and leverage strategic partnerships to achieve commercialization. We and our wholly owned subsidiaries operate in one business segment.

Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product

candidates through mid and late stages of clinical development or FDA approval. Our portfolio includes three product candidates in advanced clinical development:

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis;
- **Ovaprene®**, a hormone-free, monthly vaginal contraceptive; and
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina for treatment of female sexual arousal disorder.

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

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring for the treatment of menopausal symptoms, including vasomotor symptoms, as part of a hormone therapy following menopause;
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone- receptor positive breast cancer.

In addition, our portfolio includes these pre-clinical stage product candidates:

- **DARE-LARC1**, a combination product designed to provide long-acting, reversible contraception comprising an implantable, user-controlled wireless drug delivery system and levonorgestrel;
- **ORB-204** and **ORB-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

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

Our primary operations have consisted of, and are expected to continue to consist primarily of, product research and development and advancing our portfolio of product candidates through clinical development and regulatory approval. We expect that the majority of our research and development expenses in 2021 and 2022 will support the advancement of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any revenue. We are subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key individuals, competition from other companies, the need to develop commercially viable products in a timely and cost-effective manner, and the need to obtain adequate additional capital to fund the development of product candidates. We are also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, and product liability.

The effect of the COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain a rapidly evolving and uncertain risk to our business, operating results, financial condition and stock price. In November 2020, the U.S. began to experience a substantial surge in cases and hospitalizations and intensive care unit capacity became strained. States and counties across the country imposed or re-imposed stay-at-home orders and shutdowns of non-essential businesses in efforts to reduce spread of the disease. As of March 29, 2021, the U.S. Food and Drug Administration (FDA) had issued emergency use authorizations for three vaccines for the prevention of COVID-19. However, while President Biden recently said that there will be enough vaccine supply for every adult in the U.S. by the end of May 2021, the vaccination effort in the U.S. and elsewhere got off to a bumpy start and continues to face significant, complex challenges, and the timeline for the pandemic and its associated restrictions to end remain uncertain. Given the high level of uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, workplace environments and capital markets, we are unable to assess the full extent of the effects of the pandemic on our business. These effects could have a material adverse impact on our business, operating results and financial condition, including, without limitation, by adversely impacting our ability to raise capital when needed or on terms favorable or acceptable to us and increasing the anticipated aggregate costs and timelines for the

development and marketing approval of our product candidates. For further discussion of risks and uncertainties related to the COVID-19 pandemic, see the risk factor titled, *The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs.*

Recent Events

Positive Topline Results from DARE-BVFREE Phase 3 Clinical Trial of DARE-BV1

In December 2020, we announced positive topline results from our DARE-BVFREE Phase 3 clinical trial of DARE-BV1 for the treatment of bacterial vaginosis. The study met its primary endpoint, demonstrating that a single administration of DARE-BV1 was superior to placebo as a primary therapeutic intervention for women diagnosed with bacterial vaginosis. Based on the topline results from the DARE-BVFREE study and our meetings and other communications with the FDA since we announced those results, we plan to submit an NDA for DARE-BV1 for the treatment of bacterial vaginosis by the end of the second quarter of 2021 and to request priority review status for the NDA upon submission. Assuming we submit the NDA in the second quarter of 2021, the FDA grants priority review and sets a PDUFA date within approximately six months from the NDA submission date, and the FDA approves the NDA in 2021, we would expect a commercial launch of DARE-BV1 in the United States in early 2022. See ITEM 1. "BUSINESS—Our Clinical Stage and Phase 1-ready Product Candidates and Programs—DARE-BV1," in Part I of this report for additional information regarding the DARE-BVFREE study and the DARE-BV1 program.

Commencement of Phase 2b Clinical Trial of Sildenafil Cream, 3.6%

In March 2021, we announced commencement of our Phase 2b clinical trial of Sildenafil Cream, 3.6% for the treatment of female sexual arousal disorder. We currently anticipate reporting topline data from the trial by year-end 2021. See ITEM 1. "BUSINESS—Our Clinical Stage and Phase 1-ready Product Candidates and Programs—Sildenafil Cream, 3.6%," in Part I of this report for additional information regarding the Sildenafil Cream, 3.6% program.

Financial Overview

Revenue

To date we have not generated any revenue. In the future, and if we are successful in advancing our product candidates through late stages of clinical development and regulatory approval, we may generate revenue from product sales of approved products, if any, and license fees, milestone payments, research and development payments in connection with strategic partnerships, as well as royalties and commercial milestones resulting from the sale of products by partners. Our ability to generate such revenue will depend on the successful clinical development of our product candidates, the receipt of regulatory approvals to market such product candidates and the eventual successful commercialization of products. If we fail to complete the development of 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

Research and development expenses include research and development costs for our product candidates and transaction costs related to our acquisitions. We recognize all research and development expenses as they are incurred. Research and development expenses consist primarily of:

- expenses incurred under agreements with clinical trial sites and consultants that conduct research and development and regulatory affairs activities on our behalf;
- laboratory and vendor expenses related to the execution of nonclinical studies and clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies;
- transaction costs related to acquisitions of companies, technologies and related intellectual property, and other assets;
- milestones payments under our in-licensing arrangements and our merger agreement with Microchips that we incur, or the incurrence of which we deem probable;
- internal costs that are associated with activities performed by our research and development organization and generally benefit multiple programs.

In 2020, our research and development expenses consisted primarily of costs associated with continued development of DARE-BV1, Ovaprene and Sildenafil Cream 3.6%. We expect research and development expenses to increase in the future as we continue to invest in the development of and seek regulatory approval for our clinical-stage and Phase 1-ready product candidates and as any other potential product candidates we may develop are advanced into and through clinical trials in the pursuit of regulatory approvals. Such activities 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 research and development expenses due to, among other factors, license fee and/or milestone payments.

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. The probability of success of our product candidates may be affected by numerous factors, including clinical results and data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we cannot accurately determine the duration and completion costs of development projects or when and to what extent we will generate revenue from the commercialization of any of our product candidates.

License Fees

License fees consist of up-front license fees and annual license fees due under our in-licensing arrangements.

General and Administrative Expense

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs.

Recently Issued Accounting Standards

From time to time, the Financial Accounting Standards board, or FASB, or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through issuance of an Accounting Standards Update. We have implemented all new accounting pronouncements that are in effect and that may impact our financial statements. We have evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

Critical Accounting Policies and Estimates

Management's discussion and analysis of financial condition and results of operations is based on our 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 the financial statements. The items in our financial statements requiring significant estimates and judgments are as follows: the fair value of stock-based compensation and purchase accounting.

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 equity 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 employee 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.

The fair value of non-employee stock options or stock awards are remeasured as the awards vest, and the resulting increase or decrease in fair value, if any, is recognized as an increase or decrease to compensation expense in the period the related services are rendered. Stock options or stock awards issued to non-employees who are not

directors with performance conditions are measured and recognized when the performance is complete or is expected to be met.

Refer to Note 10 to our consolidated financial statements included in this report for more information.

Business Combinations

Assets acquired and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of the total purchase consideration over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on all available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

Acquired In-Process Research and Development Expense

We have acquired, and may continue to acquire, the rights to develop new product candidates. Payments to acquire a new product candidate, as well as future milestone payments associated with asset acquisitions which are deemed probable of achievement, are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Results of Operations

Comparison of the Years ended December 31, 2020 and 2019

The following table summarizes our consolidated results of operations for the years ended December 31, 2020 and 2019, and the change in the applicable category in terms of dollars:

	Years Ended December 31,		Change	
	2020	2019	$	%
Operating expenses:				
General and administrative	$ 6,549,508	$ 5,265,438	$ 1,284,070	24 %
Research and development	20,769,416	8,546,108	12,223,308	143 %
License fees	83,333	533,334	(450,001)	(84)%
Loss from operations	(27,402,257)	(14,344,880)	(13,057,377)	(91)%
Other income	1,514	81,050	(79,536)	(98)%
Net loss	$ (27,400,743)	$ (14,263,830)	$(13,136,913)	92 %

Revenues

We did not recognize any revenue for the years ended December 31, 2020 or 2019.

General and administrative expenses

The increase of approximately $1.3 million in general and administrative expenses from 2019 to 2020 was primarily attributable to increases in (i) personnel costs of approximately $640,000 reflecting the hiring of additional employees which resulted in increased salary, benefit and bonus expenses, (ii) expenses for legal, professional, and accounting services of approximately $212,000, (iii) insurance costs of approximately $192,000 due to increased premiums, (iv) rent and facilities expenses of approximately $183,000 due to the addition of two leases for office and laboratory facilities when we acquired Microchips in November 2019, and (v) stock-based compensation expense of approximately $161,000.

We expect an increase in general and administrative expenses of approximately 10% to 15% in 2021 compared to 2020, primarily due to increased personnel expenses and other general corporate overhead. Our 2021 general and administrative expenses could also include significant costs related to commercial readiness activities for DARE-BV1 depending on the type and nature of commercial partnership we establish for DARE-BV1 in the U.S., which, if incurred, could increase our 2021 general and administrative expenses above our current expectation.

Research and development expenses

The increase of approximately $12.2 million in research and development expenses from 2019 to 2020 was primarily attributable to increases of approximately (i) $11.6 million in costs related to development activities for our clinical-stage product candidates, primarily driven by the DARE-BVFREE Phase 3 clinical trial and manufacturing and regulatory affairs activities for Ovaprene; (ii) $2.0 million in costs related to development activities for our pre-clinical stage programs, primarily related to DARE-LARC1; (iii) $1.3 million in personnel costs reflecting our first full year of personnel costs for the former Microchips employees we hired in November 2019, and (iv) stock-based compensation expense of approximately $118,000. Those increases were partially offset by (a) an increase in grant funding recorded as a reduction to research and development expenses of approximately $2.4 million under grant awards for DARE-LARC1, Ovaprene and DARE-FRT1 and; (b) a cash payment of approximately $192,000 and a receivable of approximately $268,000, both of which are recorded as a reduction to research and development expenses and are related to Australia's research and development tax incentive which gives 43.5% of every dollar spent by eligible companies on eligible research and development activities back to those companies in a cash payment.

We expect research and development expenses to increase significantly in 2021 as we continue to develop our product candidates and seek FDA approval for DARE-BV1. If we advance our programs as currently planned, our research and development expenses for 2021 could be more than double our research and development expenses for 2020. Our 2021 research and development expenses could include up to $4.5 million in milestone payments under license agreements related to certain of our product candidates payable by us to our third-party licensors and up to approximately $1.0 million in contingent consideration payments under our merger agreement with Microchips, all or any portion of which we may elect to pay to the former stockholders of Microchips in shares of our common stock. As discussed below in the section titled “Liquidity and Capital Resources,” we will need to raise substantial additional capital to continue to fund our operations and successfully execute our current operating plan. The pace and extent of our research and development activities and, therefore, our research and development spend, will depend on our cash resources. We expect our research and development spend to vary across our fiscal quarters. In regard to Sildenafil Cream, 3.6%, we anticipate that the costs of the planned Phase 2b clinical study will be approximately $15.0 to $17.0 million, not all of which will be payable in fiscal 2021.

License fees

The $450,001 decrease in license expenses from 2019 to 2020 was attributable to a decrease in license fees accrued or paid. During 2019, we accrued or paid $533,334 of license fees under our license agreements related to DARE-HRT1 and DARE-BV1. During 2020, we accrued or paid $83,333 of license fees under our license agreement related to DARE-HRT1.

See Note 3 "License and Collaboration Agreements—In License Agreements" to the accompanying consolidated financial statements for more information about our license agreements.

Other income

The decrease of $79,536 in other income from 2019 to 2020 was primarily due to a decrease in interest earned on cash balances in 2020.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

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, we expect negative cash flows from our operations to continue for the foreseeable future, and we expect that our net losses will continue for at least the next several years as we develop and seek to bring to market our existing product candidates and potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying 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.

At December 31, 2020, our accumulated deficit was approximately $71.4 million, our cash and cash equivalents were approximately $4.7 million, and our working capital deficit was approximately $0.7 million. For the year ended December 31, 2020, we incurred a net loss of $27.4 million and had negative cash flow from operations of approximately $25.2 million.

Our primary uses of capital are, and we expect will continue to be, staff-related expenses, the cost of clinical trials and regulatory activities related to our product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments due under license agreements and our merger agreement with Microchips upon the successful achievement of milestones of our product candidates, legal expenses, other regulatory expenses and general overhead costs. Our future funding requirements could also include significant costs related to commercialization of our product candidates, if approved, depending on the type and nature of commercial partnerships we establish.

As discussed above, we expect our expenses, and in particular our research and development expenses, to increase significantly in 2021 compared to 2020 as we continue to develop and seek to bring to market our product candidates, with a focus on DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue, and we cannot anticipate if or when we will generate any revenue. We have devoted significant resources to acquiring our portfolio of product candidates and to research and development activities for our product candidates. We must obtain regulatory approvals to market and sell any of our products in the future. We will need to generate sufficient safety and efficacy data on our product candidates for them to receive regulatory approvals and to be attractive assets for potential strategic partners to license or for pharmaceutical companies to acquire, and for us to generate cash and other license fees related to such product candidates.

Based on our current operating plan estimates, we do not have sufficient cash 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 financial statements. Historically, the cash used to fund our operations has come from a variety of sources. During 2020, we received (1) approximately $15.2 million in net proceeds from ATM sales of shares of our common stock; (2) approximately $7.7 million in net proceeds from sales of shares of our common stock under our equity line; (3) approximately $2.5 million under an existing grant from the Bill & Melinda Gates Foundation that funded a portion of research and development expenses for DARE-LARC1; (4) approximately $1.8 million upon the exercise of warrants to purchase 1.8 million shares of our common stock; (5) a $1.0 million upfront non-refundable license fee payment under our license agreement with Bayer HealthCare, LLC, (6) approximately $722,000 under an existing grant from the National Institutes of Health, or NIH, that funded a portion of the Ovaprene PCT clinical study costs; (7) approximately $367,000 under a loan we obtained under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief and Economic Security Act administered by the U.S. Small Business Administration, or the SBA; and (8) approximately $192,000 in cash under Australia's research and development tax incentive program. From January 1, 2021 and through March 29, 2021, we received (a) approximately $7.4 million in net proceeds from ATM sales of shares of our common stock; (b) approximately $3.9 million in net proceeds from sales of shares of our common stock under our equity line; (c) approximately $139,000 under existing grants from the NIH that funded (i) a portion of the Ovaprene PCT clinical study costs and (ii) a portion of the research and development expenses for DARE-FRT1; and (d) approximately $50,000 upon the exercise of warrants to purchase 52,500 shares of our common stock.

We will need to raise substantial additional capital to continue to fund our operations and successfully execute our current operating plan, including the development of our product candidates. We are currently evaluating a variety of capital raising options, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover our operating expenses, including the development of our product candidates and any future product candidates we may license or otherwise acquire. The amount and timing of our capital needs have been and will continue to depend highly on many factors, including the product development programs we choose to pursue and the pace and results of our clinical development efforts. If we raise capital through collaborations, strategic alliances or other similar types of arrangements, we may have to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates we would otherwise seek to develop or commercialize. 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, particularly in light of the effects that the COVID-19 pandemic has recently had on the capital markets and investor sentiment. In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders, and debt financings may subject us to restrictive covenants, operational restrictions and security interests in our assets. 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 development programs, reduce expenses file for bankruptcy, reorganize, merge with another entity, or cease operations. 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. See ITEM 1A. "RISK FACTORS—Risks Related to Our Business—*We will*

need to raise additional capital to continue our operations and execute our current product development plans," above.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Years Ended December 31,	
	2020	2019
Net cash used in operating activities	$ (25,234,924)	$ (13,315,480)
Net cash provided by (used in) investing activities	(17,625)	6,143,893
Net cash provided by financing activities	25,130,672	5,151,702
Effect of exchange rate changes on cash and cash equivalents	11,237	(5,897)
Net decrease in cash	$ (110,640)	$ (2,025,782)

Operating activities

Cash used in operating activities during the year ended December 31, 2020 included a net loss of $27.4 million, decreased by non-cash stock-based compensation expense of $742,031. Components providing operating cash were an approximately $1.3 million increase in accrued expenses, a $1.0 million increase in deferred license revenue, a $157,725 increase in other non-current assets and deferred charges and a $95,042 increase in other receivables. Components reducing operating cash were a $454,133 increase in prepaid expenses, a $455,121 decrease in deferred grant funding, and a $61,850 decrease in accounts payable.

Cash used in operating activities during the year ended December 31, 2019 included a net loss of $14.3 million, decreased by non-cash stock-based compensation expense of $462,239. Components providing operating cash were a $621,618 increase in accrued expenses, an increase of $608,650 in accounts payable, and an increase of $237,937 in other non-current assets and deferred charges. Components reducing operating cash were a $322,482 increase in prepaid expenses, a $238,109 increase in deferred grant funding, and a $201,423 increase in other receivables.

Investing activities

Cash used in investing activities during the year ended December 31, 2020 was related to minimal purchases of property and equipment.

Cash provided by investing activities during the year ended December 31, 2019 consisted of the approximately $6.1 million of cash of Microchips as of the date we acquired Microchips.

Financing activities

Cash provided by financing activities during the year ended December 31, 2020 included approximately $15.2 million of net proceeds received from ATM sales of shares of our common stock, approximately $7.7 million of net proceeds received from sales of shares of common stock under our equity line, approximately $1.8 million received upon the exercise of warrants to purchase shares of our common stock, and approximately $367,000 in proceeds received under our PPP loan.

Cash provided by financing activities during the year ended December 31, 2019 consisted of proceeds from the underwritten public offering completed in April 2019.

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 Chief Executive Officer and Chief 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.

At the conclusion of the year ended December 31, 2020, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief 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, 2020 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, 2020 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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

In January 2018 we entered into a common stock sales agreement with H.C. Wainwright & Co., LLC, or Wainwright, relating to the offering and sale of shares of our common stock from time to time in an ATM offering through Wainwright, acting as sales agent. In accordance with the agreement, on March 29, 2021, we provided notice

to Wainwright to terminate the agreement. The agreement will terminate on April 3, 2021. Under the agreement, Wainwright was entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold under the agreement and we provided Wainwright with customary indemnification rights. We are exploring entering into a new sales agreement for an ATM offering, but there can be no assurance that we will establish a new ATM facility.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

Set forth below are the names, ages, board committee assignments, tenure, class, and certain biographical information of each of the members of our board of directors as of March 29, 2021. In accordance with our certificate of incorporation and by-laws, our board of directors is divided into three classes, with one class of directors standing for election each year, for a three-year term.

Name	Age	Committees	Director Since	Class**
Cheryl R. Blanchard	56	Compensation	November 2019	III
Jessica D. Grossman, M.D.	48	Audit, Nominating & Corporate Governance	April 2018	I
Susan L. Kelley, M.D.	66	Nominating & Corporate Governance*	October 2014	I
Sabrina Martucci Johnson	54	None	July 2017	III
Gregory W. Matz, CPA	61	Audit*	September 2018	II
William H. Rastetter, Ph.D.	72	Compensation*	January 2014	II
Robin J. Steele, J.D., L.L.M.	65	Audit, Compensation	July 2017	II

* Committee chairperson

** The term for Class I directors ends at our 2021 annual meeting of stockholders. The term for Class II and III directors ends at the annual meeting of our stockholders to be held in 2022 and 2023, respectively.

Cheryl R. Blanchard. Dr. Blanchard joined our board of directors in November 2019 following our acquisition of Microchips Biotech, Inc., or Microchips. Dr. Blanchard served as President and Chief Executive Officer of Microchips, which prior to the merger, was a venture-backed biotechnology company developing implantable drug delivery products, from 2014 through the company's acquisition by Daré. Dr. Blanchard currently serves as President and Chief Executive Officer of Anika Therapeutics, Inc., a publicly traded biotech and medical devices company, a position she has held since April 2020, and before that she served as its Interim Chief Executive Officer since February 2020. From July 2018 to July 2019, Dr. Blanchard served as President and Chief Executive Officer of Keratin Biosciences, Inc., a privately-held biotechnology company created in July 2018 by the business combination of Microchips and KeraNetics, LLC. From 2000 to 2012, Dr. Blanchard was an officer of Zimmer, Inc., a medical device company focused on musculoskeletal products, serving as Senior Vice President, Chief Scientific Officer, and general manager of Zimmer Biologics. Since 2012, Dr. Blanchard has also been a principal of Blanchard Consulting, LLC, which provides scientific, regulatory, and business strategy consulting services to medical device companies and private equity clients. Prior to Zimmer, Dr. Blanchard built and led the medical device practice at Southwest Research Institute while also serving as an adjunct professor at the University of Texas Health Science Center, both in San Antonio, Texas. Some of her work led to the creation of Keraplast Technologies, LLC. Dr. Blanchard also serves on private equity and venture backed company boards as well as the board of Anika Therapeutics, Inc. She previously served on the board of directors of SeaSpine Holdings Corporation, from July 2015 to May 2019, and of Neuronetics, Inc., from February 2019 to June 2020. In 2015, Dr. Blanchard was elected to the National Academy of Engineering, among the highest professional distinctions accorded to an engineer. Dr. Blanchard received her Masters of Science and Ph.D. in Materials Science and Engineering from the University of Texas at Austin and her Bachelor of Science in Ceramic Engineering from Alfred University. She is also a member of the National Academy of Engineering. Our board of directors believes that Dr. Blanchard is qualified to serve on our board of directors due to her extensive leadership experience with several life science companies, her experience with product development, and her experience as a director of life science companies.

Jessica D. Grossman, M.D. Dr. Grossman has been a member of our board of directors since April 2018 and currently serves as the Chief Executive Officer of IgGenix, a company developing first-in-class therapies for people limited by food allergies and other severe allergic conditions. From 2015 to 2020, Dr. Grossman served as Chief Executive Officer of Medicines360. Medicines360 is a global non-profit women’s health pharmaceutical company that developed the FDA-approved contraceptive IUD LILETTA® (52-mg levonorgestrel-releasing intrauterine system). From 2011 to 2014, Dr. Grossman served on the board of directors of Medicines360, and from 2014 to 2018 she served as Chair of AlliancePartners360, a wholly owned subsidiary of Medicines360 that serves the non-profit, public benefit mission of Medicines360 of expanding access to medicines for women regardless of their socioeconomic status, insurance coverage, or geographic location. From 2013 to 2014, Dr. Grossman served as President and

Founding Chief Executive Officer of Sense4Baby, Inc. Dr. Grossman served as a Medical Director at Ethicon Endo-Surgery, part of the Johnson & Johnson family of companies, from 2010 to 2013. From 2008 to 2010, Dr. Grossman was the Founder and Chief Executive Officer of JG Limited LLC, a consulting company providing services to medical technology companies and non-profit organizations in the areas of clinical and commercial strategy. From 2005 to 2008, Dr. Grossman was Founder and President of Gynesonics, an early stage medical device company focused on minimally invasive solutions for women's health which developed the first intrauterine ultrasound-guided radiofrequency ablation device for fibroid tumors. Dr. Grossman holds numerous patents, has published several peer-reviewed articles and conducted research at the Beth Israel Deaconess Medical Center, one of the teaching hospitals of Harvard Medical School. Dr. Grossman received her M.D. from Thomas Jefferson University, Jefferson Medical College. Our board of directors believes that Dr. Grossman is qualified to serve on our board of directors due to her extensive experience in women's health, her executive leadership experience with several life science companies, and her experience with product development and commercialization.

Susan L. Kelley, M.D. Dr. Kelley served as a member of Cerulean's board of directors beginning in October 2014 and joined the Board following the closing of the Cerulean/Private Daré stock purchase transaction. Dr. Kelley has been developing drugs in oncology and immunology for over 30 years. Dr. Kelley also serves as a member of the board of directors of Deciphera Pharmaceuticals, Inc. and IDEAYA Biosciences, Inc. From 2011 until its acquisition by Merck & Co. in 2020, Dr. Kelley served on the board of ArQule, Inc. and, from 2016 until its acquisition by Merck & Co. in 2019, she served on the board of Immune Design Corp. She was a director at VBL Therapeutics, Ltd. from 2018 until 2020. From 2008 to 2011, Dr. Kelley served as Chief Medical Officer of the Multiple Myeloma Research Consortium and its sister organization, the Multiple Myeloma Research Foundation. Previously, Dr. Kelley held positions at Bayer Healthcare Pharmaceuticals and Bayer-Schering Pharma, including Vice President, Global Clinical Development and Therapeutic Area Head—Oncology, where she led the Bayer team responsible for the development and worldwide regulatory approval of Nexavar® (sorafenib). Prior to joining Bayer, Dr. Kelley worked at Bristol-Myers Squibb in Oncology and Immunology drug development ultimately serving as Executive Director, Oncology Clinical Research, at the Bristol-Myers Squibb Pharmaceutical Research Institute. Dr. Kelley was a Fellow in Medical Oncology and Clinical Fellow in Medicine at Dana-Farber Cancer Institute, Harvard Medical School, and a Fellow in Medical Oncology and Pharmacology at Yale University School of Medicine. Dr. Kelley also serves as an Entrepreneur-in-Residence at the Yale University Office of Cooperative Research. Dr. Kelley received her M.D. from Duke University School of Medicine. Our board of directors believes that Dr. Kelley is qualified to serve on our board of directors due to her experience in life sciences and clinical development and her experience as a director of life sciences companies.

***Sabrina Martucci Johnson*.** Ms. Johnson founded Private Daré in 2015 and served as its President and CEO and as member of its board of directors since its inception and until the closing of the Cerulean/Private Daré stock purchase transaction, at which point she was appointed as Chief Executive Officer and a member of the board of directors of the combined company. Ms. Johnson is a life sciences executive committed to advancing improvements in women's healthcare. Previously, Ms. Johnson served as the Chief Financial Officer of the California Institute for Biomedical Research (now part of The Scripps Research Institute), from May of 2015 to July of 2017, and served as President of WomanCare Global Trading, a specialty pharmaceutical company in female reproductive healthcare with commercial product distribution in over 100 countries, from October of 2014 to May of 2015, and Chief Financial Officer and Chief Operating Officer from July 2013 to October 2014. Ms. Johnson provided financial consulting services to the WomanCare Global family of companies, including the United Kingdom-based non-profit division, from November 2012 to July 2013. From 2002 until its sale in 2010, Ms. Johnson served as Chief Financial Officer of Cypress Bioscience, Inc., a publicly-traded pharmaceutical company, and in addition served as its Chief Operating Officer from 2008 until its sale in 2010. Ms. Johnson began her career in the biotechnology industry as a research scientist with Baxter Healthcare, Hyland Division, working on their recombinant factor VIII program, and later held marketing and sales positions with Advanced Tissue Sciences and Clonetics Corporation. Ms. Johnson currently serves on the boards of Aethlon Medical, Inc., a publicly-traded company developing immunotherapeutic technologies to combat infectious disease and cancer; the YWCA of San Diego County, as past president; BIOCOM, as board VP of Industry, and the Clearity Foundation, as board chair. Additionally. Ms. Johnson serves on the Board of Advisors of Tulane University School of Science & Engineering, and on the Audit Committee of Project Concern International. Ms. Johnson is also past co-president of Women Give San Diego, which funds non-profit organizations serving women and girls in San Diego, and formerly served on the board of Planned Parenthood of the Pacific Southwest, Athena San Diego, and as the Chair of the University of California San Diego (UCSD) Librarian's Advisory Board. Ms. Johnson has a Masters of International Management degree with honors from the American Graduate School of International Management (Thunderbird), a MSc. in Biochemical Engineering from the University of London, University College London and a BSc. in Biomedical Engineering from Tulane University, where she graduated magna cum laude. Our board of directors believes that Ms. Johnson is qualified to serve as the Company's Chief Executive Officer and as a member of our board of directors due to her leadership experience in life sciences, women's

reproductive healthcare, development and commercial distribution of healthcare products, capital raises, and her experience as an officer in life sciences and women's reproductive healthcare non-profit and for-profit companies, including publicly traded companies.

Gregory W. Matz, CPA. Mr. Matz joined our board of directors in September 2018. Mr. Matz currently serves as a member of the board of directors of One Stop Systems, Inc. a company focused on high-performance edge computing. Mr. Matz retired as the Senior Vice President and Chief Financial Officer for The Cooper Companies in November 2016. Additionally, he served as the company's Chief Risk Officer. The Cooper Companies is a publicly traded, global medical device company that operates through two business units, CooperVision and CooperSurgical. He previously was the Vice President and Chief Financial Officer for CooperVision from May 2010 to December 2011. Prior to joining the company Mr. Matz held key management roles in finance and marketing at Agilent Technologies and Hewlett Packard. He began his career at KPMG and is a CPA with an active certification. Mr. Matz graduated from the University of San Francisco with a Bachelor of Science in Business and the University of Pennsylvania, The Wharton School's Advanced Management Program. Mr. Matz is also a National Association of Corporate Directors (NACD) Board Leadership Fellow. Our board of directors believes Mr. Matz's experience as a chief financial officer and chief risk officer of a company within the women's health industry and his corporate experience and skills in financial functions, including planning, reporting, and audit, in risk management, in managing internal growth and in capital markets and corporate strategy qualifies him to serve as a member of our board of directors and to fill the important role of "audit committee financial expert."

William H. Rastetter, Ph.D. Dr. Rastetter served as a member of Cerulean's board of directors beginning in January 2014 and as Chairman from June 2016 until the closing of the Cerulean/Private Daré stock purchase transaction, at which time he joined the board of directors of the combined company. Dr. Rastetter has been chairman of our board of directors since July 2019. Dr. Rastetter currently serves as Chairman of the board of directors of Neurocrine Biosciences, Inc. and Fate Therapeutics, Inc., and as a member of the board of directors of Grail, Inc. (a privately-held company) and of Regulus Therapeutics, Inc. Dr. Rastetter co-founded Receptos, Inc., a biopharmaceutical company, where he previously held the roles of Acting Chief Executive Officer from 2009 to 2010, and Director and Chairman of the board of directors from 2009 to 2015. Dr. Rastetter served on the board of Illumina, Inc., a leading public genomic technology company, from 1998 until January 2016, and as Chairman from 2005 to 2016. Dr. Rastetter was a Partner at the venture capital firm of Venrock Associates from 2006 to 2013. Prior to his tenure with Venrock, Dr. Rastetter was Executive Chairman of Biogen Idec Inc. and was previously Chairman and Chief Executive Officer of Idec Pharmaceuticals. Prior to Idec, he was Director of Corporate Ventures at Genentech, Inc. Dr. Rastetter held various faculty positions at the Massachusetts Institute of Technology and Harvard University and is an Alfred P. Sloan Fellow. Dr. Rastetter holds a S.B. from the Massachusetts Institute of Technology and received his M.A. and Ph.D. from Harvard University. Our board of directors believes that Dr. Rastetter is qualified to serve on our board of directors due to his extensive experience in the biotechnology industry, his broad leadership experience with several public and private biotechnology companies, and his experience with financial matters.

Robin J. Steele, J.D., LL.M. Ms. Steele served as an advisor to Private Daré since its inception in 2015 and until the closing of the Cerulean/Private Daré stock purchase transaction, at which time she joined the board of directors of the combined company. Ms. Steele previously served as Senior Vice President, General Counsel and Secretary of InterMune, Inc., a publicly-traded biopharmaceutical company, from 2004 to 2014. From 1998 to 2003, Ms. Steele served as Vice President of Legal Affairs for Elan Pharmaceuticals, a publicly traded pharmaceutical company. Ms. Steele currently serves on the board of directors of Alveo Technologies Inc., a privately-held medical diagnostics company, and Nacuity Pharmaceuticals, Inc, and GLAdiator Biosciences, both of which are privately-held biopharmaceutical companies. Ms. Steele previously served on the board of Alios Biopharma and Targanta Therapeutics, both of which were biotechnology companies focused on the research and development of therapeutic compounds prior to their respective acquisitions. Ms. Steele received a B.A. from the University of Colorado, a J.D. from the University of California, Hastings College of the Law, and an LL.M. in Taxation from New York University School of Law. Our board of directors believes that Ms. Steele is qualified to serve on our board of directors due to her expertise in legal matters, her prior experience as general counsel of a public company and her involvement with a number of private biotechnology companies.

Executive Officers

Set forth below are the names, ages, offices held, tenure, and certain biographical information of each of our executive officers as of March 29, 2021.

Name	Age	Offices	Executive Officer Since
Sabrina Martucci Johnson	54	Chief Executive Officer, President, Secretary and Director	July 2017
Lisa Walters-Hoffert	62	Chief Financial Officer	July 2017
John Fair	50	Chief Strategy Officer	March 2020

Ms. Johnson's biographical information is included above with those of the other members of our board of directors.

***Lisa Walters-Hoffert*.** Ms. Walters-Hoffert co-founded Private Daré in 2015 and served as its Chief Business Officer since its inception and until the closing of the Cerulean/Private Daré stock purchase transaction, at which time she was appointed Chief Financial Officer of the combined company. Ms. Walters-Hoffert currently serves as a member of the board of directors of Flux Power Holdings, Inc., a publicly-traded company, and as chair of its audit committee, and she has been nominated to serve on the board of directors of Altamont Pharma Acquisition Corp., a blank check company that, in March 2021, filed a registration statement under the Securities Act for its initial public offering. During the 25 years prior to founding Private Daré, Ms. Walters-Hoffert was an investment banker focused primarily on serving small-cap public companies in the technology and life sciences sectors. From 2003 to 2015, Ms. Walters-Hoffert worked for Roth Capital Partners, most recently serving as Managing Director in the Investment Banking Division, overseeing the firm's San Diego office and its activities with respect to medical device, diagnostic and specialty pharma companies. Ms. Walters-Hoffert has held various positions in the corporate finance and investment banking divisions of Citicorp Securities in San José, Costa Rica and Oppenheimer & Co, Inc. in New York City, New York. Ms. Walters-Hoffert currently serves as a member of the board of directors of the Elementary Institute of Science. She has served as a member of the board of directors of the San Diego Venture Group, as past chair of the UCSD Librarian's Advisory Board, as past chair of the board of directors of Planned Parenthood of the Pacific Southwest, and as past chair of the audit committee of the Clearity Foundation. Ms. Walters-Hoffert graduated from Duke University with a B.S. in Management Sciences, magna cum laude.

John Fair. Mr. Fair joined Daré in 2018 as its Chief Business Development Officer and was promoted to its Chief Strategy Officer in March 2020 where he is responsible for licensing, acquisitions, strategic partnering and corporate strategy. Prior to joining Daré, Mr. Fair was managing director of Capital F Consulting, a privately held consulting firm focused on healthcare consulting, capital raising and investor communications. From January 2015 to September 2016, Mr. Fair was President and Chief Operating Officer of Evofem, Inc., a specialty healthcare company developing products for women's health, microbiome and infectious disease. In that role, Mr. Fair was responsible for commercial strategy, operations and product development. From December 2012 to December 2014, Mr. Fair held senior level roles at Evofem, Inc. and its global product distribution partner, WCG. Previously, Mr. Fair served in a number of executive level roles for specialty healthcare and venture backed healthcare services businesses. Mr. Fair has a broad therapeutic experience that includes oncology, hematology, virology and women's health. Mr. Fair began his career as a portfolio strategy and insights consultant and supported numerous brands and franchises in the pharmaceutical, over-the-counter and consumer healthcare markets. Mr. Fair holds a master's degree from University of Pennsylvania, Perelman School of Medicine, a B.A. from Rider University, where he graduated magna cum laude, and has completed executive education in corporate strategy, mergers and acquisitions at Stanford University Graduate School of Business.

Family Relationships; Arrangements; Legal Proceedings

There are no family relationships among any of our directors and executive officers. There are no arrangements or understandings with another person under which our directors and officers was or is to be selected as a director or executive officer. Additionally, none of our directors or executive officers is involved in any legal proceeding that requires disclosure under Item 401(f) of Regulation S-K.

Code of Conduct and Ethics

We have adopted a Corporate Code of Conduct and Ethics and Whistleblower Policy that applies to all our employees, including our chief executive officer and chief financial and accounting officers. We will provide any person, without charge, a copy of our Corporate Code of Conduct and Ethics and Whistleblower Policy upon written request to Investor Relations, Daré Bioscience, Inc., 3655 Nobel Drive, Suite 260, San Diego, California 92122. We also post on our website a copy of our Corporate Code of Conduct and Ethics and Whistleblower Policy at www.darebioscience.com. Information contained on the website is not incorporated by reference in, or considered part of, this report. We intend to disclose any changes in our Corporate Code of Conduct and Ethics and Whistleblower Policy or waivers from it that apply to our principal executive officer, principal financial officer, or principal accounting officer by posting such information on the same website or by filing with the SEC a Current Report on Form 8-K, in each case if such disclosure is required by SEC or Nasdaq rules.

Audit Committee and Audit Committee Financial Expert

The audit committee of our board of directors is an audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. The audit committee provides advice with respect to our financial matters and assists our board of directors in fulfilling its oversight responsibilities regarding: (i) the quality and integrity of our financial statements, (ii) our compliance with legal and regulatory requirements, (iii) the evaluation of the adequacy and effectiveness of internal controls, (iv) the review and assessment of potential risk factors, (v) the review of the qualifications, independence and performance of our independent registered public accounting firm and (vi) the engagement and retention of our independent registered public accounting firm. Our board of directors has determined that each member of the audit committee—Mr. Matz, Dr. Grossman and Ms. Steele—is able to read and understand fundamental financial statements, including our balance sheet, income statement and cash flow statement. Our board of directors has also determined that Mr. Matz qualifies as an “audit committee financial expert,” as defined in Item 407(d)(5) of Regulation S-K, and that each member is independent as defined under applicable Nasdaq rules and meets the independent requirements contemplated by Rule 10-3A under the Exchange Act.

Changes in Stockholder Nomination Procedures

There have been no material changes to the procedures by which stockholders may recommend nominees to our board of directors since such procedures were last described in our proxy statement filed with the SEC on June 19, 2017.

ITEM 11. EXECUTIVE COMPENSATION

Overview

The compensation committee of our board of directors assists our board in discharging its responsibilities in respect of compensation of our executive officers. The compensation committee is currently comprised of three non-employee members of our board, Cheryl R. Blanchard, Ph.D., William H. Rastetter, Ph.D. and Robin J. Steele, J.D., L.L.M.

Executive compensation is intended to attract and retain qualified executive officers and to align the interests of our executive officers with those of our stockholders by incentivizing and rewarding achievement of business objectives that our board of directors and its compensation committee believe will enhance company value and by promoting commitment to long-term success. As a clinical-stage biopharmaceutical company, these objectives are to be accomplished primarily by positioning us to successfully execute our drug product development and regulatory approval efforts and to translate those efforts, over time, into greater value for our stockholders through revenues and income from commercialization of, or strategic collaborations with respect to, our product candidates.

Our current executive compensation program primarily includes (1) base salary, (2) annual performance-based incentive compensation, and (3) long-term incentive compensation in the form of stock options with the goal of aligning the long-term interests of executive officers with those of our stockholders and otherwise encouraging the achievement of superior results over an extended time period.

With respect to our executive compensation program, the compensation committee also: (1) reviews competitive practices and trends to determine the adequacy of our executive compensation program; (2) reviews and considers participation and eligibility in the various components of our total executive compensation package; and (3) as deemed necessary or appropriate, approves employment contracts, severance arrangements, change in control provisions and other agreements.

We have a formal policy for the timing of granting annual equity awards to our existing employees, including our named executive officers, to provide for a consistent process and to ensure the integrity and efficiency of the company's award process. Under this policy, annual equity awards will be granted on the date of the compensation committee's first regularly scheduled meeting held each year, subject to the compensation committee's ability to change the annual grant date for any particular year if the compensation committee determines that granting annual awards on such date would not be in the company's best interest.

Decisions regarding the compensation of our chief executive officer are determined by our board of directors after taking into account the recommendations of its compensation committee and the independent compensation consultant to the compensation committee. The compensation committee annually reviews and recommends to our board corporate objectives relevant to compensation of our chief executive officer, evaluates performance in light of those objectives, and recommends to our board compensation levels based on that evaluation. Our chief executive officer may not be present during any deliberations or voting with respect to her compensation. Decisions regarding the compensation of our other employees are generally determined by the compensation committee after taking into account the recommendations of its independent compensation consultant.

The table below shows the compensation awarded to or paid to, or earned by our named executive officers for the years ended December 31, 2020 and 2019. Mr. Fair was not a named executive officer for the year ended December 31, 2019, and therefore information in the table below is provided only with respect to his compensation for the year ended December 31, 2020.

2020 Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($) (1)	Non-equity incentive plan compensation ($) (2)	All Other Compensation ($) (3)	Total ($)
Sabrina Martucci Johnson	2020	$368,225	$ —	$272,845	$ 182,271	$ 13,241	$836,582
President and Chief Executive Officer	2019	$334,750	$ —	$140,534	$ 142,269	$ 11,200	$628,753
Lisa Walters-Hoffert	2020	$294,580	$ —	$ 66,262	$ 92,793	$ 12,952	$466,587
Chief Financial Officer	2019	$267,800	$ —	$ 54,051	$ 79,671	$ 11,200	$412,722
John Fair	2020	$294,580	$ —	$ 66,262	$ 92,793	$ 7,320	$460,955
Chief Strategy Officer							

(1) The amounts in this column represent the grant date fair value, determined in accordance with ASC Topic 718, Compensation-Stock Compensation (ASC Topic 718), of stock options granted to the applicable individual. See Note 10. Stock Based Compensation to our consolidated financial statements included in this report for details as to the assumptions used to determine the fair value of the awards.

(2) Amounts represent performance bonuses earned for the years indicated.

(3) Amount reflects Company 401(k) match. The Company provides the named executive officers with health, medical and other non-cash benefits generally available to all employees, which are not included in these columns pursuant to SEC rules.

Narrative to Summary Compensation Table

As reflected in the table above, the 2020 compensation of our named executive officers consisted of three primary components: (1) base salary; (2) equity compensation in the form of stock options; and (3) performance-based cash compensation.

Base Salary. The 2020 annual base salary of our named executive officers was as reported in the "salary" column of the summary compensation table.

Option Awards. Our named executive officers were each granted a stock option during 2020. Stock options are a key tool in our pay-for-performance philosophy and align the interests of our employees, including our named executive officers, with our stockholders' interests. Stock options are inherently performance-based, and automatically link executive pay to stockholder return, as the value realized, if any, by the recipient from a stock option depends upon, and directly proportionate to, the appreciation in our stock price. In preparation for making 2020 executive officer compensation decisions, our compensation committee evaluated the appropriate form of long-term incentive compensation and determined to use stock options as the primary incentive for long-term compensation in part because of the foregoing reasons.

Annual Performance-Based Bonus Opportunity. In July 2019, our board of directors, upon the recommendation of its compensation committee, established a performance-based bonus plan that provides annual bonus opportunities for all employees, including our named executive officers. The performance-based bonus plan provides for cash bonus payments based upon the achievement of performance objectives related to financial and operational metrics (the "performance objectives"), which may include, among others: developmental, clinical or regulatory milestones; business development and financing milestones; and strategic transactions. Performance goals are established for each performance period (which is generally from January 1 to December 31 of each year) by our board of directors upon the recommendation of its compensation committee or by the compensation committee. Our board of directors or its compensation committee may adjust bonuses payable under the performance-based bonus plan based on achievement of individual performance goals or pay

bonuses (including, without limitation, discretionary bonuses) to participants under the performance-based bonus plan based upon such other terms and conditions as our board of directors or its compensation committee may in their discretion determine. Each participant will have a targeted bonus opportunity set for each performance period. The achievement of the performance goals will be assessed as of the end of the applicable performance period and after such period has ended; however, if any performance goal is based on financial metrics reported in our periodic reports for any particular period, the achievement of such performance goal will be determined after the applicable periodic report has been published.

In January 2021, our board of directors met to consider, among other things, the level of achievement of the performance objectives established for the 2020 performance period under our performance-based bonus plan. The 2020 performance bonus opportunity for our employees, including our named executive officers, was based on our achievement of seven performance objectives. These objectives were established in early 2020 before the COVID-19 pandemic and did not take into account the potential impact of the pandemic on our business or operations. Five of the objectives related to the achievement of clinical or preclinical development milestones or business development goals for certain of our product candidates, including our three lead product candidates (DARE-BV1, Ovaprene® and Sildenafil Cream, 3.6%), and the other two related to securing capital to advance the development of our product candidates. The weighting for the performance objectives was up to 65% in the aggregate for the achievement of the operational and business development objectives and up to 35% in the aggregate for securing capital. The bonus amount for each employee is determined by multiplying the aggregate weighting percentage for all the performance objectives by the applicable employee's target bonus amount. The 2020 target bonus amounts for Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair were 55%, 35%, and 35%, respectively, of their respective 2020 annual base salary. The compensation committee of our board of directors and our board of directors, as the case may be, has the sole discretion to apply a weighting of 0 to 150% against the target bonus percentage. After careful review of the level of achievement of the 2020 performance objectives, our board of directors, upon the recommendation of its compensation committee, determined to award a 90% aggregate weighting to the achievement of the performance objectives for all of our employees, including our named executive officers. In determining to award a 90% aggregate weighting to the achievement of the 2020 performance objectives, our board of directors and its compensation committee considered a wide-range of factors, including, among others: the effect of the COVID-19 pandemic on our business and operations and ensuring that compensation appropriately reflects operating performance that is reasonably within management's control; the extraordinary response of our employees to the unprecedented challenges that arose during 2020 related to the pandemic, including advancing the clinical development of our product candidate programs that could be efficiently conducted during the pandemic, such as the DARE-BV1 Phase 3 clinical study and the DARE-HRT1 Phase 1 clinical study, and recalibrating the execution of our other product candidate programs, such as for Ovaprene and Sildenafil Cream, 3.6%, that could have faced challenges in the conduct of their clinical studies due to the pandemic, while maintaining the overall timelines of those product candidate programs on track by focusing instead on necessary non-clinical development activities that could be efficiently conducted during the pandemic; steps management implemented designed to protect the health and safety of our employees and other stakeholders while ensuring our ability to keep our product candidate programs on track; responsibly managing expenses without sacrificing long-term growth opportunities and the potential to achieve greater stockholder value; the influence of compensation practices on our ability to attract and retain qualified and key employees; the weight associated with each performance objective and whether the objective had been partially or fully met; the degree to which progress occurred toward the achievement of an objective; and the level of significance of achieving each objective to our company, taking into account the impact of the pandemic on our business operations and plans. Accordingly, Ms. Johnson earned a performance bonus equal to 90% of 55% of her 2020 annual base salary, or $182,271, Ms. Walters-Hoffert earned a performance bonus equal to 90% of 35% of her 2020 annual base salary, or $92,793, and Mr. Fair earned a performance bonus equal to 90% of 35% of his 2020 annual base salary, or $92,793.

In establishing the various components of our executive officer compensation program, the compensation committee considers annually, among other factors, the target total cash compensation (consisting of both base salary and target bonus amounts) of our executive officers against market data to ensure that our executive officer compensation program as a whole is positioned competitively to attract and retain qualified executive officers and that the total compensation opportunity for our executive officers is aligned with our corporate objectives and strategic needs. To make the target total cash compensation of our executive officers competitive with companies of similar size with product candidates in similar stages of development, the 2021 base salaries for each of Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair was increased by 10% and the target bonus amounts, which is at-risk pay, for the 2021 performance period for Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair was set at 70%, 40%, and 40%, respectively, of their respective 2021 annual base salaries.

Employment Agreements and Termination of Employment & Change in Control Arrangements

We have written agreements with each of Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair governing the terms of their employment with us. The following is a summary of the material terms of such agreements, as amended to date, necessary to an understanding of the information disclosed in the summary compensation table.

Each executive is eligible to receive an annual base salary, which may be adjusted at the discretion of our board.

In our sole discretion, each of our named executive officers is eligible to receive an annual bonus, the amount of which if any, will be based on the applicable executive's performance and our company's performance as measured against performance objectives and determined by the compensation committee and/or our board of directors.

Each executive is entitled to (1) participate in all equity, pension, savings and retirement plans, welfare and insurance plans, practices, policies, programs and perquisites of employment applicable generally to our senior executives, (2) receive reimbursement for reasonably incurred business expenses and (3) receive paid vacation and holiday time in accordance with policies generally applicable to our senior executives.

Subject to earlier termination, including in the event of death, the employment agreement with each of Ms. Johnson and Ms. Walters-Hoffert provides for a two-year term (which lapsed in August 2019) that automatically renews for successive one-year terms unless either party provides notice of her intent not to renew at least 60 days prior to the applicable expiration date. Ms. Johnson and Ms. Walters-Hoffert may terminate her respective employment for good reason after giving us 14 days to correct or "cure" the circumstances giving rise to a termination for good reason, or for any reason other than for good reason a upon at least 14 days' prior written notice. We may terminate the employment of Ms. Johnson and Ms. Walters-Hoffert without prior written notice for cause, without cause on 14 days' prior written notice, or in the event of the executive's disability. Their employment agreement automatically terminates upon the executive's death. Our agreement with Mr. Fair is "at will," meaning that either he or we may terminate his employment at any time and for any reason, with or without cause.

The following table summarizes our obligations and the payments and other benefits to which Ms. Johnson and Ms. Walters-Hoffert may be entitled if her employment is terminated for the reason specified, other than in connection with a change of control, which is discussed in the paragraph below the table.

Reason for Termination	Accrued Obligations[1]	Cash Payments[2]	Other Benefits[2]
• By us for cause. • By the executive without good reason. • Executive's death or disability. • Executive elects not to renew agreement.	We must pay the executive any accrued obligations as of the date of termination	None.	None.
• By us other than for cause. • By the executive with good reason. • We elect not to renew agreement.	We must pay the executive any accrued obligations as of the date of termination	We must pay the executive: [1] any accrued but unpaid bonus (or a pro rata portion of such bonus) as of the date of termination; and [2] an amount equal to a specified number of months of the executive's then-current base salary. [3]	We must provide the executive continuing health benefits coverage for a specified number of months. [3]

(1) Consists of any earned but unpaid base salary, unpaid expense reimbursements, and any vested benefits the executive may have under any employee benefit plan, in each case, as of the date of termination.

(2) Payment and benefits are conditioned on (a) the executive's continued compliance with her obligations under the employment agreement related to confidentiality and non-interference and intellectual property covenants and (b) the executive (or her estate) executing and delivering a full release of all claims in favor of Daré.

(3) The number of months is 12 for Ms. Johnson and 9 for Ms. Walters-Hoffert.

Under the terms of our employment agreements with Ms. Johnson and Ms. Walters-Hoffert, if their respective employment is terminated by us without cause or by the executive for good reason, in each case, within three months prior to or 12 months following a change of control, then, subject to the applicable executive's continued compliance with customary confidentiality, intellectual property assignment and similar obligations to us, and subject to the delivery of a full release of claims in our favor by the executive, (1) the executive is eligible to receive an amount equal to a specified number of months (18 for Ms. Johnson and 12 for Ms. Walters-Hoffert) of the executive's then-current base salary and target bonus at the rate in effect immediately prior to such termination, (2) the executive will receive continuing health benefits coverage for a specified number of months (18 for Ms. Johnson and 12 for Ms. Walters-Hoffert) and (3) any unvested and outstanding equity interests such executive may have in Daré will fully vest and accelerate.

Under the terms of our change in control policy in which our employees at vice president and above are eligible to participate, if the employment of an employee covered by such policy is terminated by us without cause or if such employee resigns for good reason, in either case, within 90 days before, or 365 days following, the effective date of a change in control, then, subject to the applicable employee's continued compliance with customary confidentiality, intellectual property assignment and similar obligations to us, and subject to the delivery of a full release of claims in our favor by such employee, the vesting of all of such employee's equity awards then outstanding that are subject solely to time-based vesting conditions that have not been satisfied will be accelerated in full. The vesting of any equity award that is subject only to performance-based vesting condition(s) or to both performance-based vesting condition(s) and time-based vesting condition(s), will not be accelerated unless such performance-based vesting condition(s) have been satisfied as of the effective date of the termination of employment or, in the case of a termination that occurs before a change in control, as of the effective date of the change in control. Mr. Fair is covered by our change in control policy, however, neither Ms. Johnson nor Ms. Walters-Hoffert are so covered.

All payments made and benefits available to each executive in connection with their employment agreement and under our change in control policy will comply with Internal Revenue Code Section 409A in accordance with the terms of such documents.

Other Benefits

We maintain a defined contribution employee retirement plan for all our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Internal Revenue Code so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. If a participant contributes 5% or more of their compensation, we match their contribution up to 4% of their annual compensation, subject to statutory limits.

We currently do not have any annuity, pension or deferred compensation plan or other arrangements for our executive officers or any employees.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning equity awards held by our named executive officers that were outstanding as of December 31, 2020:

		2020 Outstanding Equity Awards at Fiscal Year-End Option Awards			
Name	Date of Grant	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Sabrina Martucci Johnson	9/7/2018	108,000	84,000	$ 1.01	9/7/2028
	1/29/2019	93,437	101,563	$ 0.759	1/29/2029
	3/6/2020	52,500	227,500	$ 1.03	3/6/2030
Lisa Walters-Hoffert	9/7/2018	56,250	43,750	$ 1.01	9/7/2028
	1/29/2019	35,937	39,063	$ 0.759	1/29/2029
	3/6/2020	12,750	55,250	$ 1.03	3/6/2030
John Fair	9/7/2018	84,375	65,625	$ 1.01	9/7/2028
	1/29/2019	35,937	39,063	$ 0.759	1/29/2029
	3/6/2020	12,750	55,250	$ 1.03	3/6/2030

Director Compensation

With the assistance of the compensation committee, our board of directors periodically reviews and evaluates our non-employee director compensation policy. The following is an overview of our non-employee director compensation policy during 2020, which was designed to allow us to recruit and retain individuals with the requisite experience, skills and characteristics for membership on our board of directors, and to align the interests of our directors with those of our stockholders through the grant of stock options.

Retainers. Each of our non-employee directors was paid a retainer for service on our board and for each board committee on which the director served as shown in the table below. Retainers are paid in cash in arrears in four equal quarterly installments, prorated to reflect the actual time served by the director during such quarter. Directors may elect to receive up to 100% of their retainer in the form of awards of unrestricted shares of our common stock. If so elected, on the first trading day of the quarter following the quarter to which the retainer relates, we would issue a number of shares of common stock equal to (x) the amount of the cash retainer that would otherwise have been payable to such director on the date of grant divided by (y) the fair market value of our common stock on the date of grant. Directors wishing to make this election for a given calendar year must make the election on or before the last day of the prior calendar year, except that the election with respect to any year in which a director is newly elected must be made on or before June 30th of such year or such other date as determined by our board.

	Annual Retainer ($)
Board of Directors	
Chair	65,000
Member	35,000
Board Committees	
Audit Chair	20,000
Audit Member	7,500
Compensation Chair	15,000
Compensation Member	5,000
Nominating and Corporate Governance Chair	10,000
Nominating and Corporate Governance Member	3,500

Equity Awards.

Initial Award. Each director newly elected to our board receives an option to purchase 45,000 shares of our common stock, which vests as to 15,000 shares on each anniversary of the grant date until the third

anniversary of the grant date, subject to the director's continued service as a director, and will become exercisable in full upon a change in control.

Annual Award. On the date of each annual meeting of stockholders, each director that has served on our board for at least six months (and, if up for election at such annual meeting, is elected at such annual meeting) receives an option to purchase shares of our common stock, which will vest in full on the earlier of the first anniversary of the grant date or immediately prior to our first annual meeting of stockholders occurring after the grant date, subject to the director's continued service as a director, and will become exercisable in full upon a change in control. The number of shares subject to this annual option grant was 22,500 in 2020 and will be 30,000 in 2021.

The exercise price of each option granted under our non-employee director compensation policy is set at the fair market value of our common stock on the grant date.

Expense Reimbursement. We reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending board and committee meetings.

2020 Director Compensation

The following table sets forth the compensation of our non-employee directors during 2020.

2020 Director Compensation

Name	Fee Earned or Paid in Cash	Option Awards (1)	All Other Compensation	Total
Cheryl R. Blanchard, Ph.D.	$ 39,629	$ 21,806	$ —	$ 61,435
Jessica D. Grossman, M.D.	$ 46,000	$ 21,806	$ —	$ 67,806
Susan L. Kelley, M.D.	$ 45,000	$ 21,806	$ —	$ 66,806
Gregory W. Matz, CPA	$ 55,000	$ 21,806	$ —	$ 76,806
William H. Rastetter, Ph.D.	$ 80,000	$ 21,806	$ —	$ 101,806
Robin J. Steele	$ 47,500	$ 21,806	$ —	$ 69,306

(1) The amounts in this column represent the grant date fair value, determined in accordance with ASC Topic 718, Compensation-Stock Compensation (ASC Topic 718), of stock options granted to the applicable individual. See Note 10. Stock Based Compensation to our consolidated financial statements included in this report for details as to the assumptions used to determine the fair value of the awards. As of December 31, 2020, our non-employee directors had stock options outstanding to purchase the following number of shares of our common stock:

Name	# of Shares Subject to Outstanding Options
Cheryl R. Blanchard, Ph.D.	67,500
Jessica D. Grossman, M.D.	90,000
Susan L. Kelley, M.D.	97,300
Gregory W. Matz, CPA	90,000
William H. Rastetter, Ph.D.	97,301
Robin Steele, J.D.,L.L.M.	92,200

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The table below sets forth certain information, as of March 29, 2021, regarding the beneficial ownership of our common stock for (1) each person known by us to be the beneficial owner of more than 5% of our common stock, (2) each of our directors, (3) each of our named executive officers and (4) all of our current directors and executive officers as a group.

We have determined beneficial ownership in accordance with applicable SEC rules, and the information reflected in the table below is not necessarily indicative of beneficial ownership for any other purpose. Under applicable SEC rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days after the date set forth in the paragraph above through the exercise of any option, warrant or right or through the conversion of any convertible security. Unless otherwise indicated in the footnotes to the table below and subject to community property laws where applicable, we believe, based on the information furnished to us and on SEC filings, that each of the persons named in table below has sole voting and investment power with respect to the shares indicated as beneficially owned.

The information set forth in the table below is based on 47,312,822 shares of our common stock issued and outstanding on March 29, 2021. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants, rights or other convertible securities held by that person that are currently exercisable or will be exercisable within 60 days after such date. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, the address for each person listed in the table below is c/o Daré Bioscience, Inc., 3655 Nobel Drive, Suite 260, San Diego, California, 92122.

Name	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5% Stockholders		
The Vanguard Group (1)	2,993,275	6.3%
Vanguard Index Funds (2)	2,700,357	5.7%
Named Executive Officers and Directors		
Sabrina Martucci Johnson (3)	1,325,165	2.8%
Lisa Walters-Hoffert (4)	586,198	1.2%
John Fair (5)	176,020	*
Cheryl R. Blanchard, Ph.D. (6)	15,000	*
Jessica D. Grossman, M.D. (7)	52,500	*
Susan L. Kelley, M.D. (8)	59,800	*
Gregory W. Matz, CPA (9)	53,000	*
William H. Rastetter, Ph.D. (10)	70,104	*
Robin J. Steele, J.D., L.L.M. (11)	300,871	*
All directors and executive officers as a group (9 persons) (12)	2,638,658	5.5%

* Less than 1%

(1) Based on a Schedule 13G filed by The Vanguard Group, Inc. ("Vanguard Group") on February 10, 2021, reporting ownership as of December 31, 2020. According to such Schedule 13G, Vanguard Group beneficially owns 2,993,275 shares of common stock, has sole dispositive power as to 2,993,275 shares of common stock, and its address is 100 Vanguard Blvd., Malvern, PA 19355. The foregoing information has been included solely in reliance upon, and without independent investigation of, the information in such Schedule 13G.

(2) Based on a Schedule 13G filed by Vanguard Index Funds - Vanguard Total Stock Market Index Fund ("Vanguard Index Fund") on February 8, 2021, reporting ownership as of December 31, 2020. According to such Schedule 13G, Vanguard Index Fund beneficially owns 2,700,357 shares of common stock, has sole voting power as to 2,700,357 shares of common stock, and its address is 100 Vanguard Blvd., Malvern, PA 19355. The foregoing information has been included solely in reliance upon, and without independent investigation of, the information in such Schedule 13G.

(3) Includes 363,103 shares of common stock issuable upon exercise of stock options. The outstanding shares are held by The Vincent S. Johnson and Sabrina M. Johnson Family Trust dated February 14, 2005. Ms. Johnson is the co-trustee of such trust and has shared investment and dispositive power over such shares.

(4) Includes 142,686 shares of common stock issuable upon exercise of stock options. The outstanding shares are held by The Lisa Walters-Hoffert Survivor's Trust dated October 31, 2002. Ms. Walters-Hoffert is the trustee of such trust and has sole investment and dispositive power over such shares.

(5) Includes 176,020 shares of common stock issuable upon exercise of stock options.

(6) Includes 15,000 shares of common stock issuable upon exercise of stock options.

(7) Includes 52,500 shares of common stock issuable upon exercise of stock options.

(8) Includes 59,800 shares of common stock issuable upon exercise of stock options.

(9) Includes 52,500 shares of common stock issuable upon exercise of stock options. The outstanding shares are held by the Matz Trust Dated December 20, 1999. Mr. Matz is the co-trustee of such trust and has shared investment and dispositive power over such shares.

(10) Includes 59,801 shares of common stock issuable upon exercise of stock options. The outstanding shares are held by William and Marisa Rastetter Trustees of the Rastetter Family Trust U/A Dated 09/02/2010. Dr. Rastetter is the co-trustee of such trust and has shared investment and dispositive power over such shares.

(11) Includes 54,700 shares of common stock issuable upon exercise of stock options. The outstanding shares are held by the Robin J. Steele Trust DTD 1/30/2015. Ms. Steele is the trustee of such trust and has sole investment and dispositive power over such shares.

(12) Includes 976,110 shares of common stock issuable upon exercise of stock options. The members of this group are our three current executive officers (Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair) and our six non-employee directors (Drs. Blanchard, Grossman, Kelley, and Rastetter, Mr. Matz, and Ms. Steele).

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2020, with respect to compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (c) (excluding securities reflected in column a))
Equity compensation plans approved by security holders (1)	2,786,591	$ 1.16	504,516
Equity compensation plans not approved by security holders	—	$ —	—
Total	2,786,591	$ 1.16	504,516

(1) Consists of securities issued under our 2007 Stock Incentive Plan and our Amended and Restated 2014 Stock Incentive Plan, or the 2014 Plan. Under the 2014 Plan, the number of shares of common stock authorized and reserved for issuance automatically increases on an annual basis on the first day of each fiscal year, by an amount equal to the least of (i) 2,000,000 shares of common stock, (ii) 4% of the number of outstanding shares of our common stock on such date, or (iii) an amount determined by our board of directors.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Transactions

There has not been any transaction since January 1, 2019, nor is there any currently proposed, that requires disclosure Item 404 of Regulation S-K.

Company Policy Regarding Related Party Transactions

Pursuant to its charter, the audit committee of our board of directors has the responsibility to review, approve and oversee any transaction between the Company and a related person (as defined in Item 404 of Regulation S-K) and to develop policies and procedures for audit committee's approval of such transactions.

Indemnification Agreements

As permitted under Delaware law, we have entered into indemnification agreements with our officers and directors that provide that we will indemnify the 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.

Director Independence

As required under the Nasdaq listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our board of directors consults with our legal counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in Nasdaq listing standards, as in effect from time to time. Consistent with these considerations, after review of all relevant identified transactions or relationships between each of our directors, or any of his or her family members, and the Company, its senior management and its independent auditors, our board of directors affirmatively determined that all of our directors, except Ms. Johnson who is not considered independent because she is one of our executive officers, are independent directors as defined by Nasdaq Listing Rule 5605(a)(2).

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table shows the fees billed by Mayer Hoffman McCann P.C. for our last two fiscal years.

	Fiscal Year	
	2020	2019
Audit Fees (1)	$ 204,355	$ 189,180
Audit Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	—	—
Total	$ 204,355	$ 189,180

(1) Audit Fees are for professional services rendered for the audit of our annual financial statements and review of financial statements included in our Form 10-Q or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements.

(2) Audit Related Fees are for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not included in Audit Fees. No such services were rendered during 2020 or 2019.

(3) Tax Fees are for professional services for tax compliance, tax advice, and tax planning. No such services were rendered during 2020 or 2019.

(4) All Other Fees are for products and services other than the services reported above. No such services were rendered during 2020 or 2019.

Substantially all of Mayer Hoffman McCann's personnel, who work under the control of Mayer Hoffman McCann's shareholders, are employees of wholly-owned subsidiaries of CBIZ, Inc., which provides personnel and various services to Mayer Hoffman McCann in an alternate practice structure.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the audit committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the audit committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm. All audit services for 2020 were pre-approved by the audit committee.

Prior to engagement of our independent registered public accounting firm for the next year's audit, management will present to our audit committee the services expected to be required during that year for the following categories:

1. Audit services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. Audit-related services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. Tax services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. Other services are those not captured in the other categories. We generally do not request such services from our independent registered public accounting firm.

Prior to engagement, the audit committee pre-approves these services by category. The fees for these services are budgeted and our audit committee is informed periodically throughout the year of actual fees versus the budget by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, our audit committee requires specific pre-approval before engaging our independent registered public accounting firm. Our audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated, currently the audit committee chair, must report, for informational purposes only, any pre-approval decisions to the audit committee at its next scheduled meeting.

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

		Incorporated by Reference				
Exhibit Number	Description of Exhibit	Form	File No.	Filing Date	Exhibit No.	Filed Herewith
2.1§	Stock Purchase Agreement dated as of March 19, 2017, entered into by and among Cerulean Pharma Inc., Daré Bioscience, Inc. and equityholders of Daré Bioscience, Inc. named therein.	8-K	001-36395	3/20/2017	2.1	
2.2§ 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	
2.3+	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	
3.1	Restated Certificate of Incorporation, as amended by Certificate of Amendment dated July 19, 2017 to effect the Reverse Stock Split effective July 20, 2017, and by Certificate of Amendment dated July 19, 2017 stating the name change effective July 20, 2017	10-Q	001-36395	08/14/2017	3.1	
3.2	Second Amended and Restated By-Laws (as amended through June 1, 2020)	8-K	001-36395	6/3/2020	3.1	
4.1	Specimen stock certificate evidencing the shares of common stock	10-K	001-36395	03/28/2018	4.1	

4.2	Warrant, dated January 8, 2015, issued to Hercules Technology Growth Capital, Inc.	8-K	001-36395	01/08/2015	4.1
4.3	Preferred Stock Purchase Warrant to purchase shares of Series D Convertible Preferred Stock issued by the Registrant to Lighthouse Capital Partners VI, L.P., as amended	S-1	333-194442	03/10/2014	10.20
4.4	Form of Stock Purchase Warrant of the Registrant to purchase shares of Series C Convertible Preferred Stock	S-1	333-194442	03/10/2014	10.19
4.5(a)	Form of Warrant to Purchase Shares of Common Stock (February 2018 Underwritten Offering)	8-K	001-36395	02/13/2018	4.1
4.5(b)	Form of Amendment to Warrant to Purchase Common Stock entered into as of June 27, 2018	10-Q	001-36395-181175221	11/13/2018	4.1
4.6	Description of securities of the registrant	10-K	001-36395	03/27/2020	4.6
10.1Δ	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
10.2Δ	License Agreement dated March 19, 2017, between Daré Bioscience Operations, Inc. and ADVA-Tec, Inc.	10-Q	001-36395	11/13/2017	10.1
10.3(a)	Common Stock Sales Agreement, dated January 4, 2018, by and between Daré Bioscience, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-36395	01/04/2018	10.1
10.3(b)	Amendment No. 1 to Common Stock Sales Agreement, dated August 24, 2018, by and between Daré Bioscience, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-36395	08/27/2018	10.2
10.4(a)*	Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	8-K	001-36395-18949535	7/12/2018	10.1
10.4(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	08/13/2018	10.3

10.4(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	08/13/2018	10.4
10.5	Form of indemnification agreement between the registrant and each of its executive officers and directors	S-1	333-194442	03/10/2014	10.16
10.6*	Non-Employee Director Compensation Policy (as amended through April 9, 2018)	10-Q	001-36395	8/13/2018	10.2
10.7Δ	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
10.8(a)Δ	Amended and Restated Exclusive License Agreement, dated as of July 14, 2006, 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
10.8(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
10.8(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
10.8(d)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
10.8(e)Δ	Exclusive License Agreement, dated 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
10.9	2014 Employee Stock Purchase Plan	S-1/A	333-194442	03/31/2014	10.26

10.10(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)
10.10(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)
10.10(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)
10.10(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)
10.11(a)*	2007 Stock Incentive Plan	S-1	333-194442	03/10/2014	10.1
10.11(b)	Form of Incentive Stock Option Agreement under 2007 Stock Incentive Plan	S-1	333-194442	03/10/2014	10.2
10.11(c)*	Form of Nonstatutory Stock Option Agreement under 2007 Stock Incentive Plan	S-1	333-194442	03/10/2014	10.3
10.11(d)	Stock Option Agreement and Contingent Consideration Award Agreement, dated March 31, 2013, between Cerulean Pharma, Inc. and Alan Crane	S-1	333-194442	03/10/2014	10.24
10.11(e)	Amendment to the Stock Option Agreement and Termination of Contingent Consideration Award dated September 16, 2014, by and between Cerulean Pharma, Inc. and Alan Crane	10-Q	001-36395	11/13/2014	10.4
10.12(a)*	Amended and Restated 2015 Employee, Director and Consultant Equity Incentive Plan of Daré Bioscience Operations, Inc.	10-K	001-36395	03/28/2018	10.14(a)
10.12(b)*	Form of Stock Option Agreement under the Amended and Restated 2015 Employee, Director and Consultant Equity Incentive Plan of Daré Bioscience Operations, Inc.	10-K	001-36395	03/28/2018	10.14(b)
10.13(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

10.13(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)	
10.14(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	
10.14(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)	
10.15*	Daré Bioscience, Inc. Performance Bonus Plan	10-Q	001-36395	11/12/2019	10.1	
10.16+	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	
10.17	Purchase Agreement between Daré Bioscience, Inc. and Lincoln Park Capital Fund, LLC, dated April 22, 2020	8-K	001-36395	04/23/2020	10.1	
10.18	Registration Rights Agreement Between Daré Bioscience, Inc. and Lincoln Park Capital Fund, LLC, dated April 22, 2020	8-K	001-36395	04/23/2020	10.2	
10.19*	Daré Bioscience, Inc. Employment Offer Letter to John Fair, dated April 24, 2018	S-1	333-251599	01/05/2021	10.19	
10.20*	Daré Bioscience, Inc. Change in Control Policy (effective October 15, 2019)	S-1	333-251599	01/05/2021	10.20	
21.1	Subsidiaries of the registrant					X
23.1	Consent of Mayer Hoffman McCann P.C.					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of 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 pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

32.2#	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
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

§	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 30, 2021

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 Director	March 30, 2021
/s/ LISA WALTERS-HOFFERT Lisa Walters-Hoffert	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 30, 2021
/s/ WILLIAM H. RASTETTER William H. Rastetter, Ph.D.	Chairman of the Board and Director	March 30, 2021
/s/ CHERYL R. BLANCHARD Cheryl R. Blanchard, Ph.D.	Director	March 30, 2021
/s/ JESSICA D. GROSSMAN Jessica D. Grossman, M.D.	Director	March 30, 2021
/s/ SUSAN L. KELLEY Susan L. Kelley, M.D.	Director	March 30, 2021
/s/ GREGORY W. MATZ Gregory W. Matz	Director	March 30, 2021
/s/ ROBIN STEELE Robin Steele, J.D., L.L.M.	Director	March 30, 2021

DARÉ BIOSCIENCE, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
of Daré Bioscience, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of **Daré Bioscience, Inc.** and Subsidiaries ("the Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2020, 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 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company had recurring losses from operations, negative cash flow 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 described in Note 1 to the financial statements. The 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

We have served as the Company's auditor since 2017.

/s/ Mayer Hoffman McCann P.C.

March 30, 2021
San Diego, California

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31,	
	2020	2019
Assets		
Current Assets		
Cash and cash equivalents	$ 4,669,467	$ 4,780,107
Other receivables	460,168	555,210
Prepaid expenses	1,854,277	1,108,615
Total current assets	6,983,912	6,443,932
Property and equipment, net	37,930	63,531
Other non-current assets	528,870	935,325
Total assets	$ 7,550,712	$ 7,442,788
Liabilities and stockholders' equity (deficit)		
Current Liabilities		
Accounts payable	$ 1,021,333	$ 1,083,183
Accrued expenses	3,359,718	2,098,653
Deferred grant funding	1,564,553	2,019,674
Note payable	367,285	—
Current portion of contingent consideration	1,000,000	—
Current portion of lease liabilities	347,712	410,896
Total current liabilities	7,660,601	5,612,406
Deferred license revenue	1,000,000	—
Contingent consideration, net of current portion	—	1,000,000
Lease liabilities long-term	41,844	389,556
Total liabilities	8,702,445	7,001,962
Commitments and contingencies (Note 12)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value, 5,000,000 shares authorized		
None issued and outstanding	—	—
Common stock: $0.0001 par value, 120,000,000 shares authorized, 41,596,253 and 19,683,401 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	4,159	1,968
Accumulated other comprehensive loss	(91,388)	(102,625)
Additional paid-in capital	70,366,293	44,564,674
Accumulated deficit	(71,430,797)	(44,023,191)
Total stockholders' equity (deficit)	(1,151,733)	440,826
Total liabilities and stockholders' equity (deficit)	$ 7,550,712	$ 7,442,788

See Accompanying Notes to Consolidated Financial Statements.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2020	2019
Operating expenses		
General and administrative	$ 6,549,508	$ 5,265,438
Research and development	20,769,416	8,546,108
License fees	83,333	533,334
Total operating expenses	27,402,257	14,344,880
Loss from operations	(27,402,257)	(14,344,880)
Other income	1,514	81,050
Net loss	$(27,400,743)	$(14,263,830)
Deemed dividend from trigger of round down provision feature	(6,863)	(789,594)
Net loss to common shareholders	(27,407,606)	(15,053,424)
Foreign currency translation adjustments, net of tax	11,237	(5,897)
Comprehensive loss	$(27,396,369)	$(15,059,321)
Loss per common share - basic and diluted	$ (0.91)	$ (0.97)
Weighted average number of common shares outstanding:		
Basic and diluted	30,091,469	15,578,959

See Accompanying Notes to Consolidated Financial Statements.

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, 2018	**11,422,161**	**$ 1,143**	**$ 35,791,972**	**$ (96,728)**	**$ (28,969,767)**	**$ 6,726,620**
Issuance of common stock via public offering, net	5,261,250	525	5,151,177	—	—	5,151,702
Equity issued in consideration of acquisition	2,999,990	300	2,369,692	—	—	2,369,992
Stock-based compensation	—	—	462,239	—	—	462,239
Deemed dividend from trigger of down round provision	—	—	789,594	—	(789,594)	—
Net loss	—	—	—	—	(14,263,830)	(14,263,830)
Foreign currency translation adjustments	—	—	—	(5,897)	—	(5,897)
Balance at December 31, 2019	**19,683,401**	**$ 1,968**	**$ 44,564,674**	**$ (102,625)**	**$ (44,023,191)**	**$ 440,826**
Issuance of common stock	19,791,989	1,979	22,975,428	—	—	22,977,407
Issuance of common stock from the exercise of warrants	1,825,000	182	1,785,797	—	—	1,785,979
Issuance cost on equity line paid in common stock	285,714	29	291,500	—	—	291,529
Stock options exercised	10,149	1	—	—	—	1
Stock-based compensation	—	—	742,031	—	—	742,031
Deemed dividend from trigger of round down provision	—	—	6,863	—	(6,863)	—
Net loss	—	—	—	—	(27,400,743)	(27,400,743)
Foreign currency translation adjustments	—	—	—	11,237	—	11,237
Balance at December 31, 2020	**41,596,253**	**$ 4,159**	**$ 70,366,293**	**$ (91,388)**	**$ (71,430,797)**	**$ (1,151,733)**

See Accompanying Notes to Consolidated Financial Statements.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2020	2019
Operating activities:		
Net loss	$(27,400,743)	$(14,263,830)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	43,227	11,137
Stock-based compensation	742,031	462,239
Non-cash operating lease cost	(162,167)	(29,121)
Acquisition-related IPR&D	—	(202,096)
Changes in operating assets and liabilities, net of impact of acquisition:		
Other receivables	95,042	(201,423)
Prepaid expenses	(454,133)	(322,482)
Other non-current assets and deferred charges	157,725	237,937
Accounts payable	(61,850)	608,650
Accrued expenses	1,261,065	621,618
Deferred grant funding	(455,121)	(238,109)
Deferred license revenue	1,000,000	—
Net cash used in operating activities	(25,234,924)	(13,315,480)
Investing activities:		
Acquisition of Microchips cash	—	6,143,893
Purchases of property and equipment	(17,625)	—
Net cash provided by (used in) investing activities	(17,625)	6,143,893
Financing activities:		
Net proceeds from issuance of common stock	22,977,407	5,151,702
Proceeds from the exercise of common stock warrants	1,785,979	—
Proceeds from the exercise of stock options	1	—
Proceeds from issuance of note payable	367,285	—
Net cash provided by financing activities	25,130,672	5,151,702
Effect of exchange rate changes on cash and cash equivalents	11,237	(5,897)
Net change in cash and cash equivalents	(110,640)	(2,025,782)
Cash and cash equivalents, beginning of year	4,780,107	6,805,889
Cash and cash equivalents, end of year	$ 4,669,467	$ 4,780,107
Supplemental disclosure of non-cash operating, investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 583,697
Issuance cost on equity paid in common stock	$ 291,529	$ —
Deemed dividend from trigger of down round provision	$ 6,863	$ 789,594
Microchips acquisition consideration paid in equity	$ —	$ 2,369,992

See Accompanying Notes to Consolidated Financial Statements.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Organization and business

Daré Bioscience, Inc. is a clinical-stage biopharmaceutical company committed to advancing innovative products for women's health. 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 is driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. The Company's business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in the Company's areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid to late-stage clinical development, and to establish and leverage strategic partnerships to achieve commercialization.

Since July 2017, the Company has assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While the Company will continue to assess opportunities to expand its portfolio, its current focus is on advancing its existing product candidates through mid and late stages of clinical development or FDA approval. The Company's portfolio includes three product candidates in advanced clinical development:

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis;
- **Ovaprene®**, a hormone-free, monthly vaginal contraceptive; and
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina for treatment of female sexual arousal disorder;

The Company's portfolio also includes three product candidates in Phase 1 clinical development or that it believes are Phase 1-ready:

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring for the treatment of menopausal symptoms, including vasomotor symptoms, as part of a hormone therapy following menopause;
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone- receptor positive breast cancer;

In addition, the Company's portfolio includes these pre-clinical stage product candidates:

- **DARE-LARC1**, a combination product designed to provide long-acting, reversible contraception comprising an implantable, user-controlled wireless drug delivery system and levonorgestrel;
- **ORB-204 and ORB-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

The Company's primary operations have consisted of, and are expected to continue to consist primarily of, product research and development and advancing its portfolio of product candidates through clinical development and regulatory approval. The Company expects that the majority of its research and development expenses in 2021 and 2022 will support the advancement of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%.

To date, the Company has not obtained any regulatory approvals for any of its product candidates, commercialized any of its product candidates or generated any product revenue. The Company is subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key individuals, competition from other companies, the need to develop commercially viable products in a timely and cost-effective manner, and the need to obtain adequate additional capital to fund the development of product candidates. The Company is also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, and product liability.

The effect of the COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain a rapidly evolving and uncertain risk to our business, operating results, financial condition and stock price. In November 2020, the U.S. began to experience a substantial surge in cases and hospitalizations and intensive care unit capacity became strained. States and counties across the country imposed or re-imposed stay-at-home orders and shutdowns of non-essential businesses in efforts to reduce spread of the disease. As of March 29, 2021, the U.S. Food and Drug Administration (FDA) had issued emergency use authorizations for three vaccines for the prevention of COVID-19. However, while President Biden recently said that there will be enough vaccine supply for every adult in the U.S. by the end of May 2021, the vaccination effort in the U.S. and elsewhere got off to a bumpy start and continues to face significant, complex challenges, and the timeline for the pandemic and its associated restrictions to end remain uncertain. Given the high level of uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, workplace environments and capital markets, the Company is unable to assess the full extent of the effects of the pandemic on its business. These effects could have a material adverse impact on the Company's business, operating results and financial condition, including, without limitation, by adversely impacting the Company's ability to raise capital when needed or on terms favorable or acceptable to the Company, and increasing the anticipated aggregate costs and timelines for the development and marketing approval of the Company's product candidates. For further discussion of risks and uncertainties related to the COVID-19 pandemic, see the risk factor titled, *The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs.*

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, expects negative cash flows from its operations to continue for the foreseeable future, and expects that its net losses will continue for at least the next several years as it develops and seeks to bring to market its existing product candidates and 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 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, 2020, the Company had an accumulated deficit of approximately $71.4 million, had cash and cash equivalents of approximately $4.7 million, and a working capital deficit of approximately $0.7 million. For the year ended December 31, 2020, the Company incurred a net loss of $27.4 million and had negative cash flow from operations of approximately $25.2 million.

The Company’s primary uses of capital are, and the Company expects will continue to be, staff-related expenses, the cost of clinical trials and regulatory activities related to its product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments due under license agreements and its merger agreement with Microchips upon the successful achievement of milestones of the Company’s product candidates, legal expenses, other regulatory expenses and general overhead costs. The Company’s future funding requirements could also include significant costs related to commercialization of its product candidates, if approved, depending on the type and nature of commercial partnerships the Company establishes.

The Company expects its expenses, and in particular its research and development expenses, to increase significantly in 2021 compared to 2020 as it continues to develop and seek to bring to market its product candidates, with a focus on DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%

To date, the Company has not obtained any regulatory approvals for any of its product candidates, commercialized any of its product candidates or generated any product revenue, and the Company cannot anticipate if or when it will generate any revenue. The Company has devoted significant resources to acquiring its portfolio of product candidates and to research and development activities for its product candidates. The Company must obtain regulatory approvals to market and sell any of its products in the future. The Company will need to generate sufficient safety and efficacy data on its product candidates for them to receive regulatory approvals and to be attractive assets for potential strategic partners to license or for pharmaceutical companies to acquire, and for the Company to generate cash and other license fees related to such product candidates.

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 financial statements. The Company needs to raise substantial additional capital to continue to fund its operations and to successfully execute its current operating plan, including the development of its product candidates. The Company is currently evaluating a variety of capital raising options, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover its operating expenses, including the development of its product candidates and any future product candidates it may license or otherwise acquire. The amount and timing of the Company's capital needs have been and will continue to depend highly on many factors, including the product development programs the Company chooses to pursue and the pace and results of its clinical development efforts. If the Company raises capital through collaborations, strategic alliances or other similar types of arrangements, it may have to relinquish, on terms that are not favorable to the Company, rights to some of its technologies or product candidates it would otherwise seek to develop or commercialize. There can be no assurances that capital will be available when needed

or that, if available, it will be obtained on terms favorable to the Company and its stockholders, particularly in light of the effects that the COVID-19 pandemic has recently had on the capital markets and investor sentiment. In addition, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders, and debt financings may subject the Company to restrictive covenants, operational restrictions and security interests in our assets. 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Grant Funding

The Company receives certain research and development funding through grants issued by a division of the National Institutes of Health and the Bill & Melinda Gates Foundation, or the Gates Foundation. The funding is recognized in the statement 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, 2020 and December 31, 2019, the Company recognized approximately $3.7 million and $1.3 million, respectively, in the statement 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 payments 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 include the fair value of stock-based compensation, and purchase accounting. Actual results could differ from those estimates and could materially affect the reported amounts of assets, liabilities and future operating results.

Risks and Uncertainties

The Company will require approvals from the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies prior to being able to sell any products. 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 its 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, raise additional capital, compete with other products, and protect proprietary technology. In the event the Company receives a regulatory approval for a product, the market's acceptance of the product remains a risk. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

Cash and Cash Equivalents

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's wholly owned subsidiary, Microchips Biotech, Inc., has a $35,903 letter of credit related to the lease of real property that serves as security for future default of lease payments. The letter of credit is collateralized by cash which is unavailable for withdrawal or for usage for general obligations and is included in cash and cash equivalents on the Company's consolidated balance sheet.

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, 2020 and December 31, 2019. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) as of December 31, 2020.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at December 31, 2020				
Current assets:				
Cash equivalents [1]	$ 2,823,099	$ —	$ —	$ 2,823,099
Current liabilities:				
Current portion of contingent consideration [2]	$ —	$ —	$ 1,000,000	$ 1,000,000
Balance at December 31, 2019				
Current assets:				
Cash and cash equivalents	$ 4,780,107	$ —	$ —	$ 4,780,107
Other non-current liabilities:				
Contingent consideration, net of current portion [2]	$ —	$ —	$ 1,000,000	$ 1,000,000

[1] Represents the cash held in money market funds.

[2] Represents the estimated fair value of the contingent consideration potentially payable by the Company related to its acquisition of Microchips Biotech, Inc., as described in Note 4.

Revenue Recognition

The Company recognizes revenue is accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

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 and assess whether each good or service is distinct and determine those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is 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.

License Fees. 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 that are 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 not recognized any license fee revenue resulting from any of its collaborative arrangements.

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 not recognized any royalty revenue resulting from any of its collaborative arrangements.

Bayer License. In January 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. Upon execution of the agreement, the Company received a $1.0 million upfront non-refundable license fee payment from Bayer. 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 (1) 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 (2) the termination of the agreement. As of December 31, 2020, neither of the foregoing had occurred. The $1.0 million payment is recorded as long term deferred revenue in the Company's consolidated balance sheet at December 31, 2020.

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, and (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.

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, License and Collaboration Agreements.)

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use, or ROU, lease assets, current portion of lease obligations, and long-term lease obligations 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.)

Business Combinations

Assets acquired and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of the total purchase consideration over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on all available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

Acquired In-Process Research and Development Expense

The Company has acquired, and may continue to acquire, the rights to develop new product candidates. Payments to acquire a new product candidate, as well as future milestone payments associated with asset acquisitions which are deemed probable of achievement, are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. Its chief operating decision maker is the chief executive officer. The Company has one operating segment, women’s reproductive health.

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 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.

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 2,786,591 and 1,889,775 shares of common stock outstanding at December 31, 2020 and 2019, respectively. There were warrants exercisable into 1,908,643 and 3,750,833 shares of common stock outstanding at December 31, 2020 and 2019, respectively. 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. 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, volatility, 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. Additionally, the Company considered comparable companies in the industry which have available share price history to calculate the volatility. The Company compared U.S. Treasury Bills in determining the risk-free interest rate appropriate given the expected term. Finally, the Company has not established and has no plans to establish a dividend policy or declare any 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 Accounting Standards Codification, or 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 December 31, 2020, the Company did not record any liabilities for uncertain tax positions.

During each 2020 and 2019, the Company recorded no provision for income taxes. Management evaluated the Company’s tax positions and, as of December 31, 2020, the Company has approximately $1.3 million of unrecognized benefits. The tax years 2016 to 2020 remain open to examination by federal and state taxing authorities 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, 2020, 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, 2020 and 2019, no amounts have been accrued related to such indemnification provisions.

3. LICENSE AND COLLABORATION AGREEMENTS

Out-License Agreements

Bayer HealthCare License Agreement

On January 10, 2020, the Company entered into a license agreement with Bayer, regarding the further development and commercialization of Ovaprene in the U.S. Under the agreement, the Company received a $1.0 million upfront non-refundable license fee payment from Bayer. If Bayer pays an additional $20.0 million to the Company after Bayer receives and reviews the results of the pivotal clinical trial of Ovaprene, which payment Bayer may elect to make in its sole discretion, the license grant to Bayer to develop and commercialize Ovaprene for human contraception in the U.S. becomes effective.

Milestone & Royalty Payments. 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.

Efforts. The Company is responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer is supporting the Company in development and regulatory activities by providing up to two full-time equivalents with expertise in clinical, regulatory, preclinical, commercial, CMC and product supply matters in an advisory capacity. After payment of the $20.0 million 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 the Company does not receive the $20.0 million fee if and when due.

In-License Agreements

Hammock/MilanaPharm Assignment and License Agreement

In December 2018, the Company 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, 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 DARE-BV1, 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.

The following is a summary of other terms of the License Amendment, as amended:

License Fees. A total of $235,000 in license fees were payable, and were paid to, MilanaPharm: (1) $25,000 in connection with the execution of the License Amendment; (2) $100,000 in 2019; and (3) $110,000 in 2020.

Milestone Payments. The Company will pay to MilanaPharm (1) up to $300,000 in the aggregate upon achievement of certain clinical and regulatory development milestones; $50,000 of which was paid during the second quarter of 2020, and (2) up to $1.75 million in the aggregate upon achieving certain commercial sales milestones.

Foreign Sublicense Income. The Company will pay MilanaPharm 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.

Royalty Payments. During the royalty term, the Company will pay MilanaPharm 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 the Company, 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. The Company 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 the Company 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 the Company solely with respect to a licensed product or process in a country if, after having launched such product or process in such country, (1) the Company or its affiliates or sublicensees discontinue the sale of such product or process in such country and MilanaPharm notifies the Company of such termination within 60 days of having first been notified by the Company of such discontinuation, or (2) the Company or its 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 the Company.

The following is a summary of other terms of the Assignment Agreement, as amended:

Assignment; Technology Transfer. 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 to be agreed upon by the parties, with a goal for the Company to independently practice the licensed intellectual property as soon as commercially practical in order to develop and commercialize the licensed products and processes.

Fees. A total of $512,500 in fees were payable, and were paid, to Hammock: (1) $250,000 in connection with the execution of the Assignment Agreement; (2) $125,000 in 2019; and (3) $137,500 in 2020.

Milestone Payments. The Company will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones.

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.

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene and

must meet certain minimum spending amounts per year, and $5.0 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

Milestone Payments. The Company will pay to ADVA-Tec: (1) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones and (2) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones.

Royalty Payments. After the commercial launch of Ovaprene, the Company will pay to ADVA-Tec 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.

Term. Unless earlier terminated, the license continues on a country-by-country basis until the later of the life of the licensed patents or final commercial sale of Ovaprene. In addition to customary termination rights for both parties: (A) the Company 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 the Company develops or commercializes any non-hormonal ring-based vaginal contraceptive device competitive to Ovaprene or if the Company fails 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, (4) conduct clinical trials as set forth in the development plan to which the Company and ADVA-Tec agree, and as may be modified by a joint research committee, unless such failure is caused by events outside of the Company's reasonable control, or (5) enroll a patient in the first non-significant risk medical device study or clinical trial as allowed by an institutional review board within six months of the production and release of Ovaprene, unless such failure is caused by events outside of the Company's reasonable control.

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 the treatment of female sexual 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.

The following is a summary of other terms of this license and collaboration agreement:

Invention Ownership. The Company retains rights to inventions made by its employees, SST retains rights to inventions made by its employees, and each party shall own 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. The Company 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. The Company is 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 on 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 the

Company enters into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST.

Term. The Company's 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, the Company 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, the Company 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, the Company 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 the Company fails 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.

Catalent JNP License Agreement

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc. (formerly known as Juniper Pharmaceuticals, Inc., and which the Company refers to as 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. The Company is entitled to sublicense the rights granted to it under this agreement.

Upfront Fee. The Company paid a $250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement.

Annual Maintenance Fee. The Company will pay an annual license maintenance fee to Catalent on each anniversary of the date of the agreement, the amount of which will be $50,000 for the first two years and $100,000 thereafter, and which 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.

Milestone Payments. The Company must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the agreement.

Royalty Payments. During the royalty term, the Company will pay Catalent 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.

Efforts. The Company 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 the Company's uncured breach of any payment obligation under the agreement, (2) if the Company fails to maintain required insurance, (3) immediately upon the Company's insolvency or the making of an assignment for the benefit of the Company's creditors or if a bankruptcy petition is filed for or against the Company, which petition is not dismissed within 90 days, or (4) upon 60 days' notice for any

uncured material breach by the Company of any of the Company's other obligations under the agreement. The Company 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 the Company terminates 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 the Company.

Adare Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharmaceuticals (formerly known as Orbis Biosciences, and which the Company refers to as Adare), for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). Under this agreement, the Company paid Adare $300,000 to conduct the first stage of development work, Stage 1, as follows: $150,000 upon signing the agreement, $75,000 at the 50% completion point, not later than 6 months following the date the agreement was signed (which the Company paid in September 2018), and $75,000 upon delivery by Adare of the 6-month batch, not later than 11 months following the date the agreement was signed (which the Company paid in January 2019).

Upon Adare successfully completing the first stage of development work and achieving the predetermined target milestones for that stage, the Company will have 90 days to instruct Adare whether to commence the second stage of development work. Should the Company execute its option to proceed with the second stage, it will have to provide additional funding to Adare for such activities.

Pre-clinical studies for the 6- and 12-month formulations have been completed, including establishing pharmacokinetics and pharmacodynamics profiles. The collaboration with Adare will continue to advance the program through formulation optimization with the goal of achieving sustained release over the target time period.

The agreement provides the Company with an option to enter into a license agreement for ORB-204 and ORB-214 should development efforts be successful.

Acquired Products

Microchips Acquisition

As further discussed in Note 4. Acquisition below, in November 2019, the Company acquired Microchips Biotech, Inc., or Microchips. The Company acquired Microchips to secure the rights to develop an implantable, user-controlled, long-acting reversible contraception method, now known as DARE-LARC1.

The Company issued an aggregate of 2,999,990 shares of its common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger.

The Company also agreed to pay the following contingent consideration to the former Microchips 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 acquired by the Company in the merger; (c) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. The Company agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to DARE-LARC1. The Company recorded $1.0 million in contingent consideration associated with milestone payments it expects to become payable in the first half of 2021, and if and when they become due and payable, the Company may pay the milestones in cash, shares of the Company's common stock or with some combination of both.

Pear Tree Acquisition

In May 2018, the Company completed its acquisition of Pear Tree Pharmaceuticals, Inc., or Pear Tree. The Company acquired Pear Tree to secure the rights to develop a proprietary vaginal formulation of tamoxifen, now known as DARE-VVA1, as a potential treatment for vulvar and vaginal atrophy.

Milestone Payments. The Company must make contingent payments to the Pear Tree former stockholders and their representatives, or the Holders, that are based on achieving certain clinical, regulatory and commercial

milestones, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock.

Royalty Payments. The Holders will be eligible to receive, subject to certain offsets, tiered royalties, including customary provisions permitting royalty reductions and offset, based on percentages of annual net sales of certain products subject to license agreements the Company assumed and a percentage of sublicense revenue.

4. ACQUISITION

In November 2019, the Company acquired Microchips Biotech, Inc., or Microchips, via a merger transaction in which a wholly owned subsidiary the Company, formed for purposes of the transaction, merged with and into Microchips, and Microchips survived as the Company's wholly owned subsidiary. Microchips is developing a proprietary, implantable drug delivery system designed to store and precisely deliver numerous therapeutic doses over months and years on a schedule determined by the user and controlled via wireless remote. Microchips' lead product candidate is a pre-clinical stage contraceptive application of that technology that utilizes levonorgestrel, now known as DARE-LARC1.

The Company issued an aggregate of 2,999,990 shares of its common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger. The transaction was valued at $2.4 million, based on the fair value of the 2,999,990 shares issued at $0.79 per share, which was the closing price per share of the Company's common stock on the date of closing. The shares were issued in exchange for Microchips' cash and cash equivalents of $6.1 million, less net liabilities of $3.5 million and transaction costs of $202,000, which was allocated based on the relative fair value of the assets acquired and liabilities assumed.

The Company also agreed to pay contingent consideration payments, tiered royalty payments and a percentage of sublicense revenue as discussed in Note 3, Acquired Products—Microchips Acquisition, above.

The Company determined the transaction was accounted for as an asset acquisition as there were no outputs or substantive processes in existence as of the acquisition date. Transaction costs of approximately $202,000 associated with the merger were included in the Company's research and development expense in the fourth quarter of 2019.

5. PREPAID EXPENSES

Prepaid expenses consisted of the following:

	As of December 31,	
	2020	2019
Prepaid clinical expense	$ 1,288,341	$ 305,135
Prepaid insurance expense	227,298	417,152
Prepaid legal and professional expenses	338,638	386,328
Total prepaid expenses	$ 1,854,277	$ 1,108,615

6. OTHER NON-CURRENT ASSETS

Other non-current assets consisted of the following:

	As of December 31,	
	2020	2019
Prepaid insurance, long-term portion	$ 246,016	$ 404,141
Deposits	43,304	42,904
Operating lease assets	239,550	488,280
Total other non-current assets	$ 528,870	$ 935,325

7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2020	2019
Accrued compensation and benefits expenses	$ 1,157,074	$ 715,201
Accrued legal and professional expenses	297,395	412,584
Accrued license expense	66,667	280,833
Accrued clinical and related expenses	1,838,582	690,035
Total accrued expenses	$ 3,359,718	$ 2,098,653

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,	
	2020	2019
Domestic	$ 27,249	$ 13,800
Foreign	152	464
Loss before taxes	$ 27,401	$ 14,264

The difference between the provision for income taxes (benefit) and the amount computed by applying the U.S. federal income tax rate for the years ended December 31, 2020 and 2019 are as follows:

	Years Ended December 31,	
	2020	2019
Federal statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	8.86 %	7.01 %
Permanent differences	— %	(0.02)%
Research and development credit	1.80 %	1.46 %
Stock compensation	(0.34)%	(0.44)%
Other	(0.40)%	(0.1)%
Change in valuation allowance	(30.93)%	(28.94)%
Effective income tax rate	(0.01)%	(0.02)%

The major components of the Company's deferred tax assets as of December 31, 2020 and 2019 are shown below (in thousands).

	2020	2019
Net operating loss carryforwards	$ 68,437	$ 46,120
Research and development credit carryforwards	4,903	3,669
Capitalized research and development costs	9,398	11,123
Other	376	271
Stock compensation	2,183	1,987
Total deferred tax assets	85,297	63,170
Valuation allowance	(85,297)	(63,170)
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 $85.3 million and $63.2 million was established at December 31, 2020 and 2019 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 $22.1 million and $4.1 million for the years ending December 31, 2020 and 2019, respectively, is primarily related to an increase in net operating losses generated during the year.

The Company has U.S. federal net operating loss, or NOL, carryforwards available at December 31, 2020 of approximately $255.9 million (2019– $174.5 million) of which, $0.2 million begin expiring in 2021 unless previously utilized and $78.1 million that do not expire. The Company has state NOL carryforwards of $221.0 million (2019 – $140.1 million) that begin expiring in 2031 unless previously utilized. The Company has U.S. federal research credit carryforwards available at December 31, 2020 of approximately $4.0 million (2019 – $3.1 million) that begin expiring in 2027 unless previously utilized. The Company has state research credit carryforwards of $2.7 million (2019 – $1.9 million) that begin expiring in 2022 unless previously utilized. These federal and state research and development credits are subject to a 20% reserve under 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.

In March 2020, the Coronavirus Aid, Relief and Economic Security (“CARES”) Act was enacted and signed into law and GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act includes changes to the tax provisions that benefits business entities, and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act. The tax relief measures for businesses in the CARES Act include a five-year net operating loss carryback for certain net operating losses, suspension of the annual deduction limitation of 80% of taxable income for certain net operating losses, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. The CARES Act also provides other non-tax benefits to assist those impacted by the pandemic. The Company evaluated the impact of the CARES Act and determined that there is no material impact to the income tax provision for the year ended December 31, 2020.

The Consolidated Appropriation Act (“CAA”) of 2021 was signed into law in December 2020, containing COVID-19 relief provisions as well as many tax provisions including renewals of several popular tax extenders. The Company evaluated the impact of the CAA and determined that there is no material impact to the income tax provision for the year ended December 31, 2020.

A reconciliation of the beginning and ending amount of uncertain tax benefits is as follows (in thousands):

	Years Ended December 31,	
	2020	2019
Beginning uncertain tax benefits	$ 935	$ 924
Current year - increases	237	83
Prior year - additions (reductions)	169	(72)
Ending uncertain tax benefits	$ 1,341	$ 935

Included in the balance of uncertain tax benefits at December 31, 2020 are $1.3 million of tax benefits that, if recognized, would impact the effective tax rate. 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, 2020 and 2019, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The tax years 2016 through 2020 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, 2020.

9. STOCKHOLDERS' EQUITY

2018 ATM Sales Agreement

In January 2018, the Company entered into a common stock sales agreement under which the Company may sell shares of its common stock from time to time in "at the market offerings" of equity securities (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, the "Securities Act"). The Company will pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement plus certain legal expenses. The common stock sales agreement was amended in August 2018 to refer to the Company's shelf registration statement on Form S-3 (File No. 333-227019) that was filed to replace the Company's shelf registration statement on Form S-3 (File No. 333-206396) that expired on August 28, 2018.

During 2020, the Company sold 12,577,703 shares of common stock under this agreement for gross proceeds of approximately $15.8 million and incurred offering expenses of approximately $594,000. The Company did not sell any shares under this agreement during 2019.

April 2019 Underwritten Public Offering

In April 2019, the Company closed an underwritten public offering of 4,575,000 shares of its common stock at a public offering price of $1.10 per share. The Company granted the underwriters a 30-day over-allotment option to purchase up to an additional 686,250 shares which was exercised in full on April 12, 2019. Including the over-allotment shares, the Company issued a total of 5,261,250 shares in the underwritten public offering and received gross proceeds of approximately $5.8 million and net proceeds of approximately $5.2 million after deducting underwriting discounts and offering expenses.

Equity Line

On April 22, 2020, the Company entered into a purchase agreement, or the Purchase Agreement, and a 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 may occur from time to time, at the Company's sole discretion, subject to certain limitations, until May 19, 2023. On April 22, 2020, in accordance with the Purchase Agreement, the Company issued 285,714 shares of its common stock, or the Commitment Shares, to Lincoln Park in consideration for its commitment to purchase shares under the Purchase Agreement. The Company filed a registration statement on Form S-1 (File No. 333-237954) to register the resale by Lincoln Park of up to 7.5 million shares of the Company's common stock issued or issuable to Lincoln Park under the Purchase Agreement, including the Commitment Shares, and such registration statement was declared effective by the SEC on May 12, 2020. The Company filed a registration statement on Form S-1 (File No. 333-251599) to register the resale by Lincoln Park of up to 6.4 million additional shares of the Company's common stock issued or issuable to Lincoln Park under the Purchase Agreement, and such registration statement was declared effective by the SEC on January 7, 2021.

The Company incurred legal, accounting, and other fees related to the Purchase Agreement of approximately $374,000. These costs are amortized and expensed as shares are sold under the Purchase Agreement. As of December 31, 2020, there was approximately $175,000 of unamortized costs recorded as a prepaid in the Company's consolidated balance sheet. During 2020, the Company sold, and Lincoln Park purchased, 7,214,286 shares under the Purchase Agreement for gross proceeds to the Company of approximately $8.0 million and recognized offering expenses of approximately $236,000.

Under the Purchase Agreement, on any business day until May 19, 2023, the Company may direct Lincoln Park to purchase up to 200,000 shares of common stock, each, a Regular Purchase. The Company may increase the share amount it directs Lincoln Park to purchase under a Regular Purchase to up to 250,000 shares or up to 300,000 shares if the closing sale price of the Company's common stock is not below $1.50 or $3.00, respectively, on the business day on which the Company initiates the purchase, subject to adjustment for any reorganization,

recapitalization, non-cash dividend, stock split or other similar transaction as provided in the Purchase Agreement. However, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1.0 million. The purchase price per share for each Regular Purchase will be the lower of (i) the lowest sale price of the Company's common stock on the business day on which the Company initiates the purchase and (ii) the average of the three lowest closing sale prices of the Company's common stock during the 10-business day period immediately preceding the business day on which the Company initiates the purchase. In addition to Regular Purchases, the Company 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 the Company stipulates in its notice to Lincoln Park initiating these purchases.

In addition, under applicable Nasdaq rules, the Company may not issue or sell to Lincoln Park under the Purchase Agreement more than 4,941,089 shares of its common stock, or the Exchange Cap, unless (i) the Company obtains stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of the Company's common stock to Lincoln Park under the Purchase Agreement equals or exceeds $1.0117 (which represents the closing sale price per share of the Company's common stock on the day before the Company entered into the Purchase Agreement, plus an incremental amount). In addition, the Company may not sell shares to Lincoln Park under the Purchase Agreement if such sale would result in Lincoln Park beneficially owning more than 9.99% of the Company's then outstanding shares of common stock.

Common Stock Warrants

In February 2018, the Company closed an underwritten public offering in connection with which the Company issued to the investors in that offering warrants that initially had an exercise price of $3.00 per share and are exercisable through February 2023. The warrants include a price-based anti-dilution provision, which provides that, subject to certain limited exceptions, the exercise price of the warrants will be reduced each time the Company issues or sells (or is deemed to issue or sell) securities for a net consideration per share less than the exercise price of those warrants in effect immediately prior to such issuance or sale. In addition, subject to certain exceptions, if the Company issues, sells or enters into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of the Company's common stock, the warrant holders have the right to substitute such variable price for the exercise price of the warrant then in effect. These warrants are exercisable only for cash, unless a registration statement covering the shares issued upon exercise of the warrants is not effective, in which case the warrants may be exercised on a cashless basis. A registration statement covering the shares issued upon exercise of the warrants is currently effective. 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 grant date. The Company early adopted ASU 2017-11 as of January 1, 2018 and recorded the fair value of the warrants as equity.

In April 2019 and July 2020, in accordance with the price-based anti-dilution provision discussed above, the exercise price of these warrants was automatically reduced to $0.98 per share and to $0.96 per share, respectively, and as a result of the triggering of the anti-dilution provision, $0.8 million and $6,863, respectively, was recorded to additional paid-in capital.

During the year ended December 31, 2020, warrants to purchase an aggregate of 1,825,000 shares of common stock were exercised for gross proceeds of approximately $1.8 million. No warrants were exercised during the year ended 2019. As of December 31, 2020, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
2,906	$	120.40	12/01/2021
3,737	$	120.40	12/06/2021
6,500	$	10.00	04/04/2026
1,895,500	$	0.96	02/15/2023
1,908,643			

Common Stock

The authorized capital of the Company consists of 120,000,000 shares of common stock with a par value of $0.0001 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 41,596,253 and 19,683,401 shares of common stock as of December 31, 2020 and 2019, respectively. There were no shares of preferred stock outstanding as of December 31, 2020 or 2019.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2020:

Common stock reserved for issuance upon exercise of warrants outstanding	1,908,643
Common stock reserved for issuance upon exercise of options outstanding	2,786,591
Common stock reserved for future equity awards (under the Amended 2014 Plan)	504,516
Total	5,199,750

10. STOCK-BASED COMPENSATION

The 2015 Employee, Director and Consultant Equity Incentive Plan

In connection with the business combination transaction in July 2017 between the Company and Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, the Company assumed the Private Daré 2015 Employee, Director and Consultant Equity Incentive Plan, or the 2015 Private Daré Plan and each then outstanding award granted thereunder, which consisted of options and restricted stock. Based on the exchange ratio for the business combination transaction and after giving effect to the reverse stock split effected in connection with the closing of that transaction, the outstanding options and restricted stock awards granted under the 2015 Private Daré Plan were replaced with options to purchase 10,149 shares of the Company's common stock with a correspondingly adjusted exercise price and 223,295 shares of the Company's common stock. All of the options that were assumed were exercised as of December 31, 2020. No awards may be granted under the 2015 Private Daré Plan following the closing of the business combination transaction.

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 and there was no stock-based compensation related to the ESPP for the years ended December 31, 2020 or December 31, 2019.

Amended and Restated 2014 Stock Incentive Plan

The Company maintains the Amended and Restated 2014 Plan, or the Amended 2014 Plan. There were 2,046,885 shares of common stock authorized for issuance under the Amended 2014 Plan when it was approved by the Company's stockholders in July 2018. The number of authorized shares increases annually on the first day of each fiscal year until, and including, the fiscal year ending December 31, 2024 by the least of (i) 2,000,000, (ii) 4% of the number of outstanding shares of common stock on such date, or (iii) an amount determined by the Company's board of directors. As a result of the foregoing, the number of shares available under the Amended 2014 Plan increased by 787,336 to 1,411,481 on January 1, 2020, which increase represented 4% of the number of outstanding shares of common stock on such date.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Amended 2014 Plan, and related information for the years ended December 31, 2020 and 2019. The exercise price of all options granted during the years ended December 31, 2020 and 2019 was equal to the market value of the Company's common stock on the date of grant. As of December 31, 2020, unamortized stock-based compensation expense of approximately $1.3 million will be amortized over the weighted average period of 2.2 years. As of December 31, 2020, 504,516 shares of common stock were reserved for future issuance under the Amended 2014 Plan.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	1,635,790	$ 11.08		
Granted	832,500	0.79		
Exercised	—	—		
Forfeited	(578,445)	28.52		
Expired	(70)	59.48		
Outstanding at December 31, 2019 [(1)]	1,889,775	$ 1.21		
Granted	906,965	1.06		
Exercised	(10,149)	—		
Canceled/forfeited	—	—		
Expired	—	—		
Outstanding at December 31, 2020 [(1)]	2,786,591	$ 1.16	8.33	$ 993,981
Options exercisable at December 31, 2020	1,199,857	$ 1.40	8.01	$ 427,931
Options vested and expected to vest at December 31, 2020	2,786,591	$ 1.16	8.33	$ 993,981

(1) Includes 10,149 shares subject to options granted under the 2015 Private Daré Plan assumed in connection with the Cerulean/Private Daré stock purchase transaction.

Compensation Expense

Total stock-based compensation expense related to stock options granted to employees and directors recognized in the consolidated statements of operations is as follows:

	Years Ended December 31,	
	2020	2019
Research and development	$ 225,579	$ 107,142
General and administrative	516,452	355,097
Total	$ 742,031	$ 462,239

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the years ended December 31, 2020 and 2019 is as follows:

	2020	2019
Expected life in years	10.0	10.0
Risk-free interest rate	0.82 %	2.44 %
Expected volatility	120 %	120 %
Forfeiture rate	0.0 %	0.0 %
Dividend yield	0.0 %	0.0 %
Weighted-average fair value of options granted	$ 1.00	$ 0.75

11. LEASED PROPERTIES

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018 and terminates on July 31, 2021. The lease provides the Company with an option to extend the term of the lease for one year.

Microchips, which the Company acquired in November 2019, leases general office space in Lexington, Massachusetts and warehouse space in Billerica, Massachusetts. The Lexington lease commenced on July 1, 2013 and terminates on September 30, 2021. The Billerica lease commenced on October 1, 2016 and terminates on March 31, 2022.

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 of 7% for operating leases that commenced prior to January 2019 (and all of the Company's operating leases commenced prior to such date). The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At December 31, 2020, the Company reported operating lease right of use assets of approximately $240,000 in other non-current assets, and approximately $347,000 and $42,000, respectively, in current and non-current other liabilities on the consolidated balance sheet.

Total operating lease costs were approximately $303,800 and $223,000 for the years ended December 31, 2020 and 2019, 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 statement of operations.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $461,000 for the year ended December 31, 2020, and these amounts are included in operating activities in the consolidated statement of cash flows. Further, at December 31, 2020, operating leases had a weighted average remaining lease term of 0.86 years.

At December 31, 2020, future minimum lease payments under the Company's operating leases are as follows:

Year ending December 31,	
2021	$ 363,000
2022	42,000
Total future minimum lease payments	405,000
Less: accreted interest	16,000
Total operating lease liabilities	$ 389,000

12. COMMITMENTS AND CONTINGENCIES

Contingent Consideration

In connection with the acquisition of Microchips, the Company agreed to pay contingent consideration based upon the achievement of specified funding, product development and regulatory milestones. The Company recorded $1.0 million in contingent consideration liability associated with milestone payments expected to become payable in the first half of 2021 in its consolidated balance sheet at December 31, 2020.

Note Payable

In April 2020, due to the economic uncertainty resulting from the impact of the COVID-19 pandemic on the Company's operations and to support its ongoing operations and retain all employees, the Company applied for a loan under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, administered by the U.S. Small Business Administration, or the SBA. The Company received a loan of approximately $367,000. Under the terms of the PPP, the loan proceeds could be used for "qualifying expenses" and, subject to specified limitations in the CARES Act and under the terms of the PPP, certain amounts of the loan, including accrued interest, may be forgiven if used for qualifying expenses. Qualifying expenses include payroll costs, costs used to continue group health care benefits, mortgage interest payments, rent payments, utility payments, and interest payments on other debt obligations. In September 2020, the Company submitted its forgiveness application. The Company recorded a note payable plus accrued interest for the loan in the amount of approximately $369,600 in

its consolidated balance sheet at December 31, 2020. In January 2021, the Company was notified that the principal balance of the PPP loan and all accrued interest was fully forgiven by the SBA. See Note 14. Subsequent Events.

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 executive officers are entitled to payments if they are terminated without cause or as a result of a change in control of the Company. Upon termination without cause, and not as a result of death or disability, each officer is entitled to receive a payment of an amount equal to six to twelve months of base salary and to receive continuing health benefits coverage for periods ranging between six to twelve months following the termination of employment or until such officer is covered under a separate plan from another employer. Upon termination other than for cause or for good reason within three months prior to or twelve months following a change in control of the Company, each officer will be entitled to receive a payment of an amount equal to nine to eighteen months of base salary and target bonus and to receive continuing health benefits coverage for periods ranging between nine to 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.

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 salary. The Company made matching contributions of approximately $136,000 and $96,000 during the years ended December 31, 2020 and 2019, respectively.

13. GRANT AWARDS

NIH Grant Funding

The Company has received notices of awards and grant funding from the National Institutes of Health, or the NIH, to support the development of Ovaprene and DARE-FRT1. The NIH issues 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 statement of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

Ovaprene

Since 2018, the Company has received approximately $1.9 million of grant funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a division of the NIH, for clinical development efforts supporting Ovaprene. The most recent and final notice of award the Company received was for approximately $731,000 in April 2020, substantially all of which has been funded to date.

The Company recorded credits to research and development expense for costs related to the NIH award of approximately $595,000 and $1.2 million for the years ended December 31, 2020 and December 31, 2019, respectively. At December 31, 2020, the Company recorded a receivable of approximately $12,000 for expenses incurred through such date that it believes are eligible for reimbursement under the final notice of award received in April 2020.

DARE-FRT1

In August 2020, the Company received a notice of award of a grant from the NIH to support the development of DARE-FRT1. The award in the amount of $300,000 was for what is referred to as the "Phase I" segment of the project outlined in the Company's grant application, which is to occur during the period of August 2020 through July 2021. Additional potential funding of up to approximately $2.0 million for the "Phase II" segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds. There is no guarantee the Company will receive any Phase II award.

The Company recorded credits to research and development expense for costs related to the NIH award of approximately $131,000 for the year ended December 31, 2020. At December 31, 2020, the Company recorded a receivable of approximately $128,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

Bill & Melinda Gates Foundation

The Company's wholly-owned subsidiary, Microchips, has a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation, relating to the development of the pre-clinical stage contraceptive candidate, DARE-LARC1. Expenses eligible for grant funding must be incurred, tracked and reported to the Foundation. Microchips received grant funding payments of approximately $2.9 million in 2019 and $2.5 million in 2020. At December 31, 2020, grant funding payments associated with research and development expenses for DARE-LARC1 not yet incurred totaled approximately $1.6 million and are recorded as deferred grant funding liability in the Company's consolidated balance sheet.

14. SUBSEQUENT EVENTS

ATM Sales

Between January and March 2021, the Company sold an aggregate of 3,264,069 shares of common stock in at the market offerings through a sales agent and received aggregate gross proceeds of approximately $7.7 million and incurred sales agent commissions and fees of approximately $245,000 (see Note 9).

Equity Line

Between January and March 2021, the Company sold an aggregate of 2,400,000 shares of common stock to Lincoln Park under the Purchase Agreement and received aggregate net proceeds of approximately $3.9 million.

Exercise of February 2018 Warrants

In February 2021, warrants to purchase an aggregate of 52,500 shares of common stock were exercised at an exercise price of $0.96 per share resulting in gross proceeds to the Company of approximately $50,000 (see Note 9).

PPP Loan Forgiveness

In January 2021, the Company was notified that the principal balance of its PPP loan and all accrued interest was fully forgiven by the SBA. The Company will record a gain contingency and debt forgiveness income with respect to such loan forgiveness in the first quarter of 2021.

Leased Properties

On January 7, 2021, the Company exercised its option to extend the term of the lease for its corporate headquarters in San Diego, California for a year. The extended term begins August 1, 2021 and expires July 31, 2022.

On January 25, 2021, the Company entered into an amendment extend the term of the lease for its office space in Lexington, Massachusetts for a year. The extended term begins October 1, 2021 and expires September 30, 2022.