UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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 Number: 001-36395

DARÉ BIOSCIENCE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation)		**20-4139823** (IRS Employer Identification No.)
3655 Nobel Drive, Suite 260 **San Diego, CA** (Address of Principal Executive Offices)	**(858) 926-7655** (Registrant's telephone number, including area code)	**92122** (Zip Code)

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**DARE**	**Nasdaq Capital Market**

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 x No o

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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company, or 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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	o		

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 pursuant to Section 13(a) of the Exchange Act. o

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

As of November 8, 2023, 98,562,344 shares of the Registrant's Common Stock, par value $0.0001, were issued and outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, in particular "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," of Part I. Financial Information, and the information incorporated by reference herein contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, projected revenue, funding and expenses, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "pursue," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions.

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

- *Inability to raise additional capital, under favorable terms or at all, to fund our operating needs and continue as a going concern;*
- *Failure to complete development of our product candidates or submit and obtain United States Food and Drug Administration, or FDA, or foreign regulatory authority approval for our product candidates on projected timelines or budgets, or at all;*
- *Inability to demonstrate sufficient safety and efficacy of our product candidates;*
- *The timely supply of XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO, and our clinical trial supplies, including their components as well as the finished product, in the quantities needed in accordance with current good manufacturing practices, our specifications and other applicable requirements;*
- *The performance of third parties on which we rely to conduct nonclinical studies and clinical trials of our product candidates;*
- *Our failure, or a failure of a strategic collaborator, to successfully commercialize our product candidates, if approved, or our failure to otherwise monetize our portfolio programs and assets;*
- *The timing and amount of future royalty and milestone payments to us, if any, under our out-license agreements for commercialization of XACIATO and Ovaprene®;*
- *Termination by a collaborator of our respective out-license agreements for commercialization of XACIATO and Ovaprene, or, in the case of Ovaprene, a decision by the collaborator not to make the license grant fully effective following its review of the results of a pivotal clinical trial of Ovaprene;*
- *The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;*
- *Difficulties with maintaining existing collaborations relating to the development and/or commercialization of our product candidates, or establishing new ones on a timely basis or on acceptable terms, or at all;*
- *The terms and conditions of any future strategic collaborations relating to our product candidates;*
- *The degree of market acceptance that XACIATO and any future product achieves;*
- *Coverage and reimbursement levels for XACIATO and any future product by government health care programs, private health insurance companies and other third-party payors;*
- *Our loss of, or inability to attract, key personnel;*
- *A change in the FDA's prior determination that the Center for Devices and Radiological Health would lead the review of a premarket approval application for potential marketing approval of Ovaprene;*
- *A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b)(2) of the 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;*
- *Unfavorable differences between preliminary, interim or topline clinical study data reported by us and final study results;*
- *Communication from the FDA or another regulatory authority, including a complete response letter, that such agency does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that such agency interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *Failure to select product candidates that capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas within women's health including due to our limited financial resources;*
- *Loss or impairment of our in-licensed rights to develop and commercialize XACIATO and our product candidates;*
- *Our payment and other obligations under our in-license and acquisition agreements for XACIATO and our product candidates;*
- *Developments by our competitors that make XACIATO, or any potential product we develop, less competitive or obsolete;*
- *Macroeconomic factors, including inflation, interest rates and recessionary pressures, geopolitical conflicts and events, public health emergencies such as the COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat or natural disasters;*
- *Weak interest in women's health relative to other healthcare sectors from the investment community or from pharmaceutical companies and other potential development and commercialization collaborators;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems and data, our financial resources and other assets, or the technology systems and data of third parties on which we rely;*
- *Difficulty in introducing branded products in a market made up of generic products;*
- *Inability to adequately protect or enforce our, or our licensor’s, intellectual property rights;*
- *Lack of patent protection for the active ingredients in XACIATO and certain of our product candidates that expose them to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Dependence on grant funding for preclinical development of DARE-LARC1 and DARE-LBT;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results or results that differ from investors' expectations for such results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could cause investors to experience losses and subject us to securities class-action litigation;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *Development of safety, efficacy or quality concerns related to our product or product candidates (or third-party products or product candidates that share similar characteristics or drug substances), whether or not scientifically justified, leading to delays in or discontinuation of product development, product recalls or withdrawals, diminished sales, and/or other significant negative consequences;*
- *Product liability claims or governmental investigations;*

- *Changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, pricing and/or marketing of our products, product candidates and related intellectual property, health care information and data privacy and security laws, transparency laws and fraud and abuse laws, and the enforcement thereof affecting our business; and*
- *Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.*

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

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

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 13,894,424	$ 34,669,605
Other receivables	1,129,759	1,703,160
Prepaid expenses	6,579,933	6,665,988
Other current assets	831,379	—
Total current assets	22,435,495	43,038,753
Property and equipment, net	58,623	64,908
Deposits	1,763,477	10,502
Other non-current assets	796,435	712,220
Total assets	$ 25,054,030	$ 43,826,383
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 4,987,397	$ 2,027,953
Accrued expenses	5,293,246	10,894,016
Deferred grant funding	15,662,335	18,303,567
Deferred revenue	205,206	—
Current portion of lease liabilities	194,586	398,391
Total current liabilities	26,342,770	31,623,927
Deferred revenue, non-current	1,000,000	1,000,000
Lease liabilities long-term	—	90,346
Total liabilities	27,342,770	32,714,273
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value, 5,000,000 shares authorized; None issued and outstanding	—	—
Common stock, $0.0001 par value; 240,000,000 shares authorized; 98,292,344 and 84,825,481 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	9,829	8,482
Accumulated other comprehensive loss	(419,497)	(351,311)
Additional paid-in capital	164,299,397	152,529,579
Accumulated deficit	(166,178,469)	(141,074,640)
Total stockholders' equity (deficit)	(2,288,740)	11,112,110
Total liabilities and stockholders' equity (deficit)	$ 25,054,030	$ 43,826,383

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Loss
(**Unaudited**)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue				
License fee revenue	$ 1,000,000	$ —	$ 1,000,000	$ 10,000,000
Total revenue	1,000,000	—	1,000,000	10,000,000
Operating expenses				
General and administrative	2,696,779	2,651,543	8,954,877	8,014,424
Research and development	6,674,636	4,462,250	17,738,543	17,065,497
License fee expense	25,000	25,000	75,000	75,000
Total operating expenses	9,396,415	7,138,793	26,768,420	25,154,921
Loss from operations	(8,396,415)	(7,138,793)	(25,768,420)	(15,154,921)
Other income	97,319	118,950	664,591	150,406
Net loss	$ (8,299,096)	$ (7,019,843)	$ (25,103,829)	$ (15,004,515)
Net loss to common shareholders	$ (8,299,096)	$ (7,019,843)	$ (25,103,829)	$ (15,004,515)
Foreign currency translation adjustments	(15,030)	(230,748)	(68,186)	(375,767)
Comprehensive loss	$ (8,314,126)	$ (7,250,591)	$ (25,172,015)	$ (15,380,282)
Loss per common share - basic and diluted	$ (0.09)	$ (0.08)	$ (0.29)	$ (0.18)
Weighted average number of shares outstanding:				
Basic and diluted	91,051,642	84,822,516	87,221,575	85,553,134

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)

Nine Months Ended September 30, 2023

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount				
Balance at December 31, 2022	**84,825,481**	**$ 8,482**	**$ 152,529,579**	**$ (351,311)**	**$(141,074,640)**	**$ 11,112,110**
Stock-based compensation	—	—	624,621	—	—	624,621
Issuance of common stock from the exercise of warrants	1,353,515	136	1,299,239	—	—	1,299,375
Net loss	—	—	—	—	(8,042,501)	(8,042,501)
Foreign currency translation adjustments	—	—	—	(22,005)	—	(22,005)
Balance at March 31, 2023	**86,178,996**	**$ 8,618**	**$ 154,453,439**	**$ (373,316)**	**$(149,117,141)**	**$ 4,971,600**
Stock-based compensation	—	—	650,186	—	—	650,186
Issuance of common stock, net of issuance costs	454,592	45	452,150	—	—	452,195
Net loss	—	—	—	—	(8,762,232)	(8,762,232)
Foreign currency translation adjustments	—	—	—	(31,151)	—	(31,151)
Balance at June 30, 2023	**86,633,588**	**$ 8,663**	**$ 155,555,775**	**$ (404,467)**	**$(157,879,373)**	**$ (2,719,402)**
Stock-based compensation	—	—	636,086	—	—	636,086
Issuance of common stock and warrants, net of issuance costs	11,658,756	1,166	8,107,536	—	—	8,108,702
Net loss	—	—	—	—	(8,299,096)	(8,299,096)
Foreign currency translation adjustments	—	—	—	(15,030)	—	(15,030)
Balance at September 30, 2023	**98,292,344**	**$ 9,829**	**$ 164,299,397**	**$ (419,497)**	**$(166,178,469)**	**$ (2,288,740)**

Nine Months Ended September 30, 2022

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2021	**83,944,119**	**$ 8,394**	**$ 149,027,802**	**$ (154,973)**	**$(110,126,902)**	**$ 38,754,321**
Stock-based compensation	—	—	532,409	—	—	532,409
Net loss	—	—	—	—	(8,398,670)	(8,398,670)
Foreign currency translation adjustments	—	—	—	(9,150)	—	(9,150)
Balance at March 31, 2022	**83,944,119**	**$ 8,394**	**$ 149,560,211**	**$ (164,123)**	**$(118,525,572)**	**$ 30,878,910**
Stock-based compensation	—	—	537,521	—	—	537,521
Issuance of common stock, net of issuance costs	751,040	75	1,218,675	—	—	1,218,750
Stock options exercised	125,699	13	120,136	—	—	120,149
Net income	—	—	—	—	413,998	413,998
Foreign currency translation adjustments	—	—	—	(135,869)	—	(135,869)
Balance at June 30, 2022	**84,820,858**	**$ 8,482**	**$ 151,436,543**	**$ (299,992)**	**$ (118,111,574)**	**$ 33,033,459**
Stock-based compensation	—	—	556,448	—	—	556,448
Stock options exercised	4,623	—	4,456	—	—	4,456
Net loss	—	—	—	—	(7,019,843)	(7,019,843)
Foreign currency translation adjustments	—	—	—	(230,748)	—	(230,748)
Balance at September 30, 2022	**84,825,481**	**$ 8,482**	**$ 151,997,447**	**$ (530,740)**	**$(125,131,417)**	**$ 26,343,772**

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (25,103,829)	$ (15,004,515)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	28,383	13,580
Stock-based compensation expense	1,910,893	1,626,378
Non-cash operating lease cost	(18,602)	29,320
Gain on early termination of lease	—	(46,477)
Changes in operating assets and liabilities:		
Other receivables	573,401	(1,146,724)
Prepaid expenses	86,053	(4,408,886)
Deposits	(1,752,975)	—
Other current assets	(831,379)	77,939
Other non-current assets	(24,764)	—
Accounts payable	2,959,446	1,374,109
Accrued expenses	(6,068,350)	1,000,086
Deferred grant funding	(2,641,232)	4,293,433
Deferred revenue	205,206	—
Net cash used in operating activities	(30,677,749)	(12,191,757)
Cash flows from investing activities		
Purchases of property and equipment	(22,099)	(60,372)
Net cash used in investing activities	(22,099)	(60,372)
Cash flows from financing activities		
Net proceeds from issuance of common stock and warrants	8,560,897	1,218,750
Proceeds from the exercise of stock options	—	124,605
Proceeds from the exercise of common stock warrants	1,299,375	—
Issuance of note payable	601,174	—
Payments on note payable	(133,594)	—
Net cash provided by financing activities	10,327,852	1,343,355
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(68,185)	(375,767)
Net change in cash, cash equivalents and restricted cash	(20,440,181)	(11,284,541)
Cash, cash equivalents and restricted cash, beginning of period	34,669,605	51,674,087
Cash, cash equivalents and restricted cash, end of period	$ 14,229,424	$ 40,389,546
Reconciliation of cash, cash equivalents and restricted cash to amounts reported in the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 13,894,424	$ 40,389,546
Restricted cash included in other non-current assets	335,000	—
Total cash, cash equivalents and restricted cash	$ 14,229,424	$ 40,389,546
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities, net	$ —	$ 585,942

See accompanying notes.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Daré Bioscience, Inc. is a 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 began assembling its diverse portfolio in 2017 through acquisitions, exclusive in-licenses and other collaborations. The Company's programs target unmet needs in women's health in the areas of contraception, vaginal health, reproductive health, menopause, sexual health, and fertility, and aim to expand treatment options, enhance outcomes and improve ease of use for women.

The Company's primary operations have consisted of, and are expected to continue to consist primarily of, research and development activities to advance its product candidates through clinical development and regulatory approval.

The Company's portfolio includes one FDA-approved product, drug and drug/device product candidates and potential product candidates in various stages of development.

The first shipment of the Company's product, XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO, in connection with the first commercial sale of the product in the United States occurred in October 2023. XACIATO was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In March 2022, the Company entered into an exclusive global license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO, which became fully effective in June 2022. Under the license agreement, the marketing, distribution and sale of XACIATO in the United States (and outside the U.S. if approved in non-U.S. jurisdictions in the future) will be by Organon and/or its affiliates, agents or sublicensees.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as defined by the Financial Accounting Standards Board, or FASB, for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management's opinion, the accompanying condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results of the interim periods presented.

Interim financial results are not necessarily indicative of results anticipated for any other interim period or for the full year. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, or the 2022 10-K.

Cash, Cash Equivalents and Restricted Cash

The Company considers cash and all highly liquid investments with an original maturity of three months or less to be cash and cash equivalents. The Company has an aggregate of approximately $0.3 million in restricted cash related to (i) letters of credit established under real property leases for the Company's wholly owned subsidiary, Dare MB Inc., that serve as security for potential future default of lease payments, and (ii) collateralized cash for the Company's credit cards. The restricted cash is unavailable for withdrawal or for usage for general obligations and are included in other non-current assets on the Company's consolidated balance sheets.

Going Concern

The Company prepared its condensed 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 to potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

As of September 30, 2023, the Company had an accumulated deficit of approximately $166.2 million, cash and cash equivalents of approximately $13.9 million, deferred grant funding liabilities under the Company's grant agreements related to DARE-LARC1 and DARE-LBT of approximately $15.7 million, and a working capital deficit of approximately $3.9 million. Substantially all of the Company's cash and cash equivalents at September 30, 2023 represented grant funds received under such grant agreements that may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support the entire operations of the Company. For the nine months ended September 30, 2023, the Company incurred a net loss of approximately $25.1 million and had negative cash flow from operations of approximately $30.7 million.

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 condensed consolidated financial statements. The Company will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current strategy.

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will not be able to continue development of its product candidates, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If the Company becomes unable to continue as a going concern, the Company may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its condensed consolidated financial statements, and stockholders may lose all or part of their investment in the Company's common stock. The Company's condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company’s significant accounting policies are described in Note 2 to the consolidated financial statements included in the 2022 10-K. Since the date on which the 2022 10-K was filed with the U.S. Securities and Exchange Commission, or the SEC, there have been no material changes to the Company’s significant accounting policies.

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 September 30, 2023 and December 31, 2022. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) or using unobservable inputs (Level 3) as of September 30, 2023 or December 31, 2022.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at September 30, 2023				
Current assets:				
Cash equivalents [1]	$ 13,528,906	$ —	$ —	$ 13,528,906
Balance at December 31, 2022				
Current assets:				
Cash equivalents [1]	$ 33,238,658	$ —	$ —	$ 33,238,658

[1] Represents cash held in money market funds.

Revenue Recognition

Under Accounting Standards Codification Topic 606, or ASC 606, the Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligations. At contract inception, the Company assesses the goods or services agreed upon within each contract, assesses whether each good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company develops estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Collaboration Revenues. The Company enters into collaboration and licensing agreements under which it out-licenses certain rights to its products or product candidates to third parties. The terms of these arrangements typically include payment of one or more of the following to the Company: non-refundable, up-front license fees; development, regulatory and/or commercial milestone payments; and royalties on net sales of licensed products. As of September 30, 2023, the Company has not recognized any collaboration revenues.

License Fee Revenue. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. To date, the Company has recognized $11.0 million in license fee revenue, $10.0 million of which represents the upfront payment under its license agreement for XACIATO and $1.0 million of which represents the payment required by the first amendment to such license agreement entered into in July 2023.

The Company also has a $1.0 million upfront non-refundable license fee payment from collaborator Bayer HealthCare LLC, or Bayer, recorded as deferred license revenue in the Company's consolidated balance sheets at September 30, 2023 and December 31, 2022. In 2020, the Company entered into a license agreement with Bayer regarding the further development and commercialization of Ovaprene in the U.S. and received a $1.0 million upfront non-refundable license fee payment from Bayer. (See Note 3, Strategic Agreements.) Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $20.0 million. The Company concluded that there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (i) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (ii) the termination of the agreement. As of September 30, 2023, neither of the foregoing had occurred.

Milestone Payments. At the inception of each arrangement in which the Company is a licensor and that includes developmental, regulatory or commercial milestones, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Potential future milestone payments not within the Company's control, such as where achievement of the specified milestone depends on activities of a third party or regulatory approval, are not considered probable of being achieved until the specified milestone occurs. As of September 30, 2023, the Company has not recognized any milestone payment revenues.

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). As of September 30, 2023, the Company has not recognized any royalty revenues.

Product Supply. Arrangements that include a promise for future supply of product for commercial supply at the licensee’s discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company evaluates whether it is the principal or agent in the arrangement. The evaluation is based on the degree the Company controls the specified product at any time before transfer to the customer. Revenues are recognized on a gross basis if the Company is in the capacity of principal and on a net basis if the Company is in the capacity of an agent. As of September 30, 2023, the Company has not recognized any product supply revenues.

3. STRATEGIC AGREEMENTS

Strategic Agreements for Product Commercialization

Organon Exclusive License Agreement

In March 2022, the Company entered into an exclusive license agreement with Organon, which became effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property controlled by the Company. In July 2022, the Company received a $10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue. In July 2023, the Company entered into an amendment to the license agreement whereby Organon agreed to pay $1.0 million to the Company as reimbursement for registration fees paid to the FDA in connection with the new drug application for XACIATO (known as PDUFA fees) and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, which was recognized as license fee revenue. The amount payable by Organon to the Company in connection with the first commercial sale of a licensed product in the United States was revised to $1.8 million.

Under the terms of the license agreement, as amended, the Company is entitled to receive tiered double-digit royalties based on net sales and up to $181.8 million in milestone payments as follows: $1.8 million in connection with the first commercial sale of a licensed product in the United States; and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets.

At the inception of the license agreement, the Company concluded that the transaction price was $10.0 million and should not include the variable consideration related to unachieved development, regulatory, commercial milestones and future sales-based royalty payments. This consideration was determined to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue. The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. For the quarter ended September 30, 2023, the transaction price was updated to $11.0 million.

The Company will recognize any consideration related to sales-based payments, including milestones and royalties which relate predominantly to the license granted, at the later of (i) when or as the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company is responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumes such responsibilities. Until such time, Organon will purchase all of its product requirements of XACIATO from the Company at a transfer price equal to the Company's manufacturing costs plus a single-digit percentage markup.

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

Bayer HealthCare License Agreement

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

The Company concluded there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (i) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (ii) the termination of the agreement. As of September 30, 2023, neither of the foregoing had occurred. The $1.0 million payment is recorded as long-term deferred license revenue in the Company's consolidated balance sheets at September 30, 2023 and December 31, 2022.

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

The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S. or 15 years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days' notice and the agreement will automatically terminate if the Company does not receive the $20.0 million fee if and when due.

Strategic Agreements for Pipeline Development

Douglas License Agreement

In August 2023, the Company entered into a license agreement with Douglas Pharmaceuticals Limited, or Douglas, and a stand-by direct license agreement with The University of Manchester, or Manchester, under which the Company acquired the exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia (CIN).

Under the terms of the Douglas agreement, the Company agreed to make potential future payments of up to $5.25 million in the aggregate upon achievement of certain development and regulatory milestones, and of up to $64.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement. The development and regulatory milestones may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock. Additionally, Douglas is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement. As of September 30, 2023, no payments had been made under the Douglas agreement.

Hennepin License Agreement

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

Under the terms of the license agreement, the Company agreed to make potential future payments of up to $6.25 million in the aggregate upon achievement of certain development and regulatory milestones, and up to $45.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock. Additionally, Hennepin is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement. As of September 30, 2023, no payments have been made under this agreement.

MBI Acquisition

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

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

In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events. In accordance with the terms of the merger agreement, the Company's board of directors elected to pay a portion of these milestone payments in shares of the Company's common stock, and in September 2021, the Company issued approximately 700,000 shares of its common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders' representative in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

TriLogic and MilanaPharm License Agreement / Hammock Assignment Agreement

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

Under the terms of the License Agreement, the Company paid clinical and regulatory development milestones in the aggregate of $300,000 to MilanaPharm, the final payment of $250,000 was expensed in 2021. The Company may also pay MilanaPharm up to $500,000 upon the first commercial sale in the United States of the first licensed product for each vaginal and urological use, and up to $250,000 upon the first commercial sale in the United States of each successive licensed products for each vaginal or urological use. In accordance with the terms of the License Agreement, the first commercial sale of XACIATO in the U.S. triggers a $500,000 payment to MilanaPharm. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products the Company must pay MilanaPharm $1.0 million. MilanaPharm is also eligible to receive (a) a low double-digit percentage of all income received by the Company or its affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions, and (b) high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes.

Hammock assigned and transferred to the Company all of its right, title and interest in and to the MilanaPharm license agreement and agreed to cooperate to transfer to the Company all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan. Hammock is eligible to receive up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $850,000 of which has been paid as of September 30, 2023.

Pear Tree Acquisition

In May 2018, the Company acquired Pear Tree Pharmaceuticals, Inc., or Pear Tree, to secure exclusive, sublicensable, worldwide rights under certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration. This acquisition led to the Company's DARE-VVA1 program.

Under the terms of the merger agreement, the Company agreed to pay the former stockholders of Pear Tree: (a) up to $15.5 million in the aggregate upon achievement of certain clinical development and regulatory milestones by licensed products, and (b) up to $47.0 million in the aggregate upon achievement of certain commercial milestones by licensed products. Additionally, the former stockholders of Pear Tree are eligible to receive tiered royalties based on single-digit to low double-digit percentages of annual net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, and a portion of royalties the Company receives from sublicensees. Both the milestone and royalty payments may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the merger agreement. Under the merger agreement, in addition to customary royalty reductions and offsets, royalty payments and payments based on income received from sublicensees of licensed products made by the Company to Pear Tree's licensors are creditable against all royalty and sublicense revenue share payments payable to the former stockholders of Pear Tree.

The Company agreed to pay licensors of Pear Tree (a) up to approximately $3.2 million in the aggregate upon achievement of certain clinical development, regulatory and commercial milestones by each licensed product, and (b) semi-annual royalties based on a single-digit percentage of net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, or a portion of any royalties the Company or its affiliates receives from sublicensees, and a low double-digit percentage of all sublicensing fees or other lump sum payments or compensation the Company receives from sublicensees, subject to customary exclusions. The milestone payments to the licensors of Pear Tree may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the license agreements. Portions of certain milestone payments made to Pear Tree's licensors may be creditable against royalty payments due to Pear Tree's licensors.

Catalent JNP License Agreement

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc., or Catalent, under which Catalent granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, to make, have made, use, have used, sell, have sold, import and have imported products and processes, and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Catalent to make, have made, use, have used, sell, have sold, import and have imported products and processes. The Company is entitled to sublicense the rights granted to it under this agreement.

Under the terms of the license agreement, the Company paid a $250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement and will pay a $100,000 annual license maintenance fee on each anniversary of the date of the agreement. The annual maintenance fee will be creditable against royalties and other payments due to Catalent in the same calendar year but may not be carried forward to any other year. Catalent is eligible to receive up to (a) $13.5 million in the aggregate in payments based on the achievement of specified development and regulatory milestones, $1.0 million of which has been paid as of September 30, 2023; and (b) up to $30.3 million in the aggregate in payments based on the achievement of specified commercial sales milestones for each product or process covered by the licenses granted under the agreement. Additionally, Catalent is eligible to receive mid single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, the Company will pay Catalent a low double-digit percentage of all sublicense income the Company receives for the sublicense of rights under the agreement to a third party.

Adare Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharmaceuticals USA, Inc., or Adare, for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which the Company refers to as DARE-204 and DARE-214, respectively). The agreement, as amended, provides the Company with an option to negotiate an exclusive, worldwide, royalty-bearing license, with rights to sublicense, for the programs if the Company funds the conduct of specified development work. The Company has no obligation to exercise its option.

SST License and Collaboration Agreement

In February 2018, the Company entered into a license and collaboration agreement with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC, referred to collectively as SST, under which the Company received an exclusive, royalty-bearing, sublicensable license to develop and commercialize, in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of female sexual arousal disorder and/or female sexual interest/arousal disorder, or the Field of Use, SST’s topical formulation of Sildenafil Cream, 3.6% as it existed as of the effective date of the agreement, or any other topically applied pharmaceutical product containing sildenafil or a salt thereof as a pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen, or the Licensed Products.

SST will be eligible to receive payments of up to $18.0 million in the aggregate upon achievement of certain clinical and regulatory milestones in the U.S. and worldwide, and up to $100.0 million in the aggregate upon achievement of certain commercial sales milestones. If the Company enters into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST. Additionally, SST is eligible to receive tiered royalties based on percentages of annual net sales of licensed products in the single-digit to mid double-digits subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

ADVA-Tec License Agreement

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

Under the terms of the license agreement, the Company will pay ADVA-Tec (a) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones, $1.2 million of which has been paid; and (b) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones.

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

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

4. STOCKHOLDERS' EQUITY

Increase in Authorized Shares of Common Stock

In July 2022, following the approval of the Company's stockholders at its annual meeting of stockholders, the Company amended its restated certificate of incorporation to increase the Company's authorized shares of common stock to 240,000,000.

September 2023 Registered Direct Offering

On August 29, 2023, the Company entered into a securities purchase agreement with an institutional investor and an investor affiliated with Douglas for the purchase and sale of 10,000,000 shares of the Company's common stock and warrants to purchase an aggregate of 10,000,000 shares of the Company's common stock in a registered direct offering priced at-the-market under Nasdaq rules. Each warrant is exercisable for one share of the Company's common stock. The terms of the warrants are further described below in this Note 4. The offering price was $0.70 per share of common stock and accompanying warrant. The aggregate gross proceeds to the Company from the offering were $7.0 million, and net proceeds were approximately $6.8 million. The offering was made pursuant to the Company's registration statement on Form S-3 (File No. 333-254862), filed with the SEC on March 30, 2021, and declared effective by the SEC on April 7, 2021, and a prospectus supplement thereunder. The offering closed on September 1, 2023.

March 2023 ATM Sales Agreement

In March 2023, the Company entered into a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, and Cantor Fitzgerald & Co., or Cantor, to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program under which Stifel and Cantor act as the Company's agents. The Company agreed to pay a commission equal to 3% of the gross proceeds of any common stock sold under the agreement or such lower amount as the Company and Stifel and Cantor agree, plus certain legal expenses. Shares of the Company's common stock sold under the agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-254862), the base prospectus included therein, originally filed with the SEC on March 30, 2021 and declared effective by the SEC on April 7, 2021, the prospectus supplement dated March 31, 2023 relating to the offering of up to $50.0 million of shares of the Company's common stock under the sales agreement, and any subsequent prospectus supplement related to the offering of shares of the Company's common stock under the sales agreement. During the nine months ended September 30, 2023, the Company sold 2,113,348 shares of common stock under this agreement and received aggregate gross proceeds of approximately $1.8 million and incurred sales agent commissions and fees of approximately $41,000.

October 2021 ATM Sales Agreement

In October 2021, the Company entered into a sales agreement with SVB Securities LLC (formerly known as SVB Leerink LLC) to sell shares of its common stock from time to time through an ATM equity offering program under which SVB Securities acted as the Company's agent. During the nine months ended September 30, 2023 and 2022, the Company sold zero and 751,040 shares of its common stock under the agreement, respectively. The Company terminated the agreement in March 2023.

Common Stock Warrants

September 2023 Warrants

In connection with the registered direct offering completed in September 2023, the Company issued to the investors in that offering warrants to purchase up to an aggregate of 10,000,000 shares of the Company's common stock. The warrants will be exercisable six months after issuance. The warrants have a term of five and one-half years from the date of issuance and an exercise price of $0.77 per share, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. A holder (together with its affiliates) may not exercise any portion of a warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company's outstanding common stock immediately after exercise. The warrants include certain rights upon “fundamental transactions” as described in the warrants, including the right of the holders thereof to receive from the Company or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of the Company's common stock in such fundamental transaction in the amount of the Black-Scholes value (as described in the warrants) of the unexercised portion of the applicable warrants on the date of the consummation of such fundamental transaction.

The warrants were allocated a value of $2.9 million using a Black-Scholes option pricing model based on the relative fair value method as they were issued with common stock. The Black-Scholes model used the following assumptions: expected volatility: 87.77%; risk-free interest rate: 4.29%; expected dividend yield: 0%; and expected term: 5.5 years. The warrants were deemed to be classified as equity and recorded within additional paid in capital on the condensed consolidated balance sheets. As of September 30, 2023, none of the warrants have been exercised.

February 2018 Warrants

In connection with an underwritten public offering in February 2018, the Company issued to the investors in that offering, warrants exercisable through February 15, 2023 with an initial exercise price of $3.00 per share. The Company estimated the fair value of the warrants as of February 15, 2018 to be approximately $3.0 million which was recorded in equity as of the grant date. The warrants included a price-based anti-dilution provision, which resulted in automatic reductions to the exercise price of the warrants in April 2019 and July 2020 to $0.98 per share and to $0.96 per share, respectively.

Summary of Warrant Activity

During the nine months ended September 30, 2023, February 2018 warrants to purchase 1,353,515 shares of common stock were exercised for gross proceeds of approximately $1.3 million and the remaining unexercised February 2018 warrants expired on February 15, 2023. No warrants were exercised during the nine months ended September 30, 2022.

As of September 30, 2023, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
10,000,000	$	0.77	03/01/2029
6,500	$	10.00	04/04/2026
10,006,500			

5. STOCK-BASED COMPENSATION

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan, or the ESPP, became effective in April 2014, but no offering period has been initiated thereunder since January 2017. There was no stock-based compensation related to the ESPP for the nine months ended September 30, 2023 or September 30, 2022.

Amended and Restated 2014 Stock Incentive Plan

The Amended and Restated 2014 Stock Incentive Plan, or the Amended 2014 Plan, provided for the grant of options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, officers and directors, and consultants and advisors. 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 increased annually on the first day of each fiscal year 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. On January 1, 2022, the number of authorized shares increased by 2,000,000 to 2,201,855. As a result of the approval of the 2022 Plan (as defined below) by the Company's stockholders on June 23, 2022, no further awards have been or will be granted under the Amended 2014 Plan. Outstanding awards previously granted under the Amended 2014 Plan continue to remain outstanding in accordance with their terms.

2022 Stock Incentive Plan

In April 2022, the Company's board of directors approved the Daré Bioscience, Inc. 2022 Stock Incentive Plan, or the 2022 Plan, which was subsequently approved by the Company's stockholders on June 23, 2022, and became effective as of that date. The 2022 Plan provides for the grant of stock-based incentive awards to employees, consultants, advisors, and directors.

The number of shares of common stock authorized for issuance under the 2022 Plan is (a) 10,117,305; plus (b) up to 6,144,682 shares subject to awards granted under the Amended 2014 Plan or the 2007 Stock Incentive Plan that expire, terminate or are otherwise forfeited on or after June 23, 2022.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Company's stock incentive plans and related information for the nine months ended September 30, 2023. The exercise price of all options granted during the nine months ended September 30, 2023 was equal to the market value of the Company's common stock on the date of grant. As of September 30, 2023, unamortized stock-based compensation expense of approximately $4.9 million will be amortized over a weighted average period of 2.27 years. The number of shares of common stock available for future awards granted under the 2022 Plan at September 30, 2023 was 6,725,247.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2022	6,612,554	$ 1.60
Granted	2,857,665	1.13
Exercised	—	—
Cancelled/forfeited	(6,331)	1.17
Expired	—	—
Outstanding at September 30, 2023	9,463,888	$ 1.46
Exercisable at September 30, 2023	5,225,163	$ 1.50

Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 207,081	$ 168,323	$ 617,580	$ 514,875
General and administrative	429,006	388,125	1,293,313	1,111,503
Total	$ 636,087	$ 556,448	$ 1,910,893	$ 1,626,378

6. LEASED PROPERTIES

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018. In February 2022, the Company entered into an amendment to extend the term of the lease for two years such that the term now expires on August 31, 2024.

MBI, a wholly owned subsidiary the Company acquired in November 2019, leases general office and laboratory space in Lexington, Massachusetts. The lease for that space commenced on July 1, 2013. In February 2022, the Company entered into an amendment to extend the term of the lease for three years to December 31, 2025, subject to the landlord's right to terminate the lease on December 31, 2023. The extension of the lease in February 2022 resulted in an increase in operating lease liabilities and ROU assets of approximately $1.0 million. In September 2022, the landlord exercised its option to terminate the lease, resulting in the new lease term ending on December 31, 2023. The termination of the lease resulted in a reduction of operating lease liabilities and ROU assets of approximately $504,000 and $458,000, respectively, and a $46,000 gain on the modification of the lease which was included as a reduction to research and development expense for the year ended December 31, 2022. MBI entered into a new lease for general office space and laboratory space in June 2023 that will commence on November 1, 2023 and will create an obligation to pay approximately $1.4 million over the lease period of three years.

MBI previously leased warehouse space in Billerica, Massachusetts, under a lease that commenced on October 1, 2016 and terminated 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 consisting of the current prime rate plus 200 basis points 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 September 30, 2023, the Company reported operating lease ROU assets of approximately $182,000 in other non-current assets, approximately $195,000 in current portion of lease liabilities, and approximately $0 in lease liabilities long-term in the condensed consolidated balance sheets.

Total operating lease costs were approximately $125,000 and $409,000 for the three and nine months ended September 30, 2023, respectively, and $116,000 and $469,000 for the three and nine months ended September 30, 2022, 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 condensed consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $105,516 and $314,774 for the three and nine months ended September 30, 2023, respectively, and $81,000 and $231,000 for the three and nine months ended September 30, 2022, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. At September 30, 2023, operating leases had a weighted average remaining lease term of 0.58 years.

As of September 30, 2023, future minimum lease payments under the Company's operating leases are as follows (does not include any minimum lease payments under the lease MBI entered in June 2023 because the lease does not commence until November 1, 2023):

Remainder of 2023	$	107,000
2024		93,000
Total future minimum lease payments		200,000
Less: accreted interest		5,000
Total operating lease liabilities	$	195,000

7. COMMITMENTS AND CONTINGENCIES

Insurance Financing

In July 2023, the Company obtained financing for certain director and officer and other liability insurance premiums. The agreement for such financing assigns to the lender a first priority lien on and a security interest in the financed insurance policies and any additional premium required in the financed insurance policies including (a) all returned or unearned premiums, (b) all additional cash contributions or collateral amounts assessed by the insurance companies in relation to the financed insurance policies and financed by the lender, (c) any credits generated by the financed insurance policies, (d) dividend payments, and (e) loss payments which reduce unearned premiums. If any circumstances exist in which premiums related to any financed insurance policy could become fully earned in the event of loss, the lender will be named a loss-payee with respect to such policy.

The total premiums, taxes and fees financed was approximately $0.8 million with an annual interest rate of approximately 8.0%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreement. The Company will make monthly installment payments on the financed amount through April 20, 2024. The financed amount is recognized as an insurance financing cost included in other current assets and accrued expenses in the Company's consolidated balance sheets. At September 30, 2023, the Company's remaining obligation under the agreement was approximately $0.5 million.

CRADA with NICHD for the Pivotal Phase 3 Study of Ovaprene

In July 2021, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene, or the Ovaprene Phase 3. The Ovaprene Phase 3 will be conducted within NICHD’s Contraceptive Clinical Trial Network with NICHD's contract research organization providing clinical coordination and data collection and management services for the Ovaprene Phase 3. The Company and NICHD will each provide medical oversight and final data review and analysis for the Ovaprene Phase 3 and will work together to prepare the final report of the results of the Ovaprene Phase 3. The Company is responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in payments to NICHD to be applied toward the costs of conducting the Ovaprene Phase 3. NICHD is responsible for the other costs related to the conduct of the Ovaprene Phase 3. In accordance with the payment schedule under the CRADA, the Company has made aggregate payments of $5.0 million to NICHD, $3.5 million of which was paid in 2022. The Company's remaining obligation under the CRADA at September 30, 2023 was $0.5 million.

8. GRANT AWARDS

NICHD Non-Dilutive Grant Funding

The Company has received notices of awards and non-dilutive grant funding from NICHD to support the development of DARE-PTB1, DARE-LARC1, DARE-204/214 and DARE-PTB2. NICHD 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 statements of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

DARE-PTB1

In August 2020, the Company received a notice of award of a grant from NICHD to support the development of DARE-PTB1. The award of approximately $300,000 was to be used for what is referred to as the "Phase I" segment of the project outlined in the Company's grant application. The Phase I segment ended in July 2023. 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. No determination has been received by the Company to date as to whether the Company will receive any funding for the Phase II segment and there is no guarantee the Company will receive any such funding.

The Company recorded credits to research and development expense for costs related to the NICHD award of $100 and $1,000 during the three and nine months ended September 30, 2023, respectively, and $459 and $19,911 during the three and nine months ended September 30, 2022, respectively. No receivable was recorded at September 30, 2023 or December 31, 2022. The Company received aggregate reimbursements under the NICHD award of approximately $216,000 during the grant period, which ended in July 2023. No further funds are available under this award for the Phase I segment.

DARE-LARC1

In September 2021, the Company received a notice of award of a grant from NICHD to support the development of DARE-LARC1. The award in the amount of approximately $300,000 was to be used to explore device insertion and removal in nonclinical studies.

The Company recorded credits to research and development expense of approximately $0 and $32,000 for costs related to the NICHD award during the three and nine months ended September 30, 2023, respectively, and $3,000 and $196,000 for the three and nine months ended September 30, 2022, respectively. The Company recorded a receivable of approximately $33,000 at December 31, 2022 for expenses incurred through such date that were subsequently reimbursed under the grant. No receivable was recorded at September 30, 2023. The Company received aggregate reimbursements under the NICHD award of approximately $278,000 during the grant period, which ended in June 2023. No further funds are available under this award.

DARE-204 and DARE-214

In May 2022, the Company received a notice of award of a grant from NICHD of approximately $249,000 to support end-user research to better understand women's preferences for a long-acting injectable contraceptive method. The findings from the research will inform the Company's target product profile and guide its development priorities for DARE-204 and DARE-214.

The Company recorded credits to research and development expense of approximately $32,000 and $113,000 for costs related to the NICHD award during the three and nine months ended September 30, 2023, respectively, and approximately $65,000 for each of the three and nine months ended September 30, 2022. The Company recorded a receivable of approximately $65,000 and $24,000 at September 30, 2023 and December 31, 2022, respectively, for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

DARE-PTB2

In July 2023, the Company received a notice of award of a grant from NICHD of approximately $385,000 to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds will support activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida, or USF, which are to occur over a 12-month period.

The Company recorded credits to research and development expense of approximately $600 for costs related to the NICHD award during the three and nine months ended September 30, 2023. The Company recorded a receivable of approximately $600 at September 30, 2023 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

Other Non-Dilutive Grant Funding

The Company has received funding to support the preclinical development of DARE-LARC1 and DARE-LBT under grant agreements it entered into with the Bill & Melinda Gates Foundation, or the Foundation, in June 2021 and November 2022, respectively. The Company is required to apply the funds it receives under the agreements solely toward direct costs for the applicable funded projects, other than approximately 10% of such funds, which it may apply toward general overhead and administration expenses that support the entire operations of the Company. The Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Funds received that have not been spent are recorded as cash and cash equivalents and as a deferred grant funding liability in our condensed consolidated balance sheets. Our deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. The grant agreements include the Foundation's standard discretionary termination provisions. Any grant funds that have not been used or committed to the funded project must be returned promptly to the Foundation upon expiration or termination of the agreement.

2022 DARE-LBT Grant Agreement

In November 2022, the Company entered into an agreement with the Foundation under which the Company was awarded $585,000 to support the development of DARE-LBT. The Company received the full amount of the award in November 2022. As of September 30, 2023, the Company recorded a deferred grant funding liability of approximately $464,000 in the Company's condensed consolidated balance sheets.

2021 DARE-LARC1 Grant Agreement

In June 2021, the Company entered into an agreement with the Foundation under which the Company was awarded up to approximately $49.0 million to support the development of DARE-LARC1. The agreement supports technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 in nonclinical proof-of-principle studies. As of September 30, 2023, the Company has received a cumulative total of approximately $28.3 million in non-dilutive funding under the agreement: approximately $11.5 million in 2021, approximately $12.4 million in 2022, and $4.5 million in 2023. Additional payments are contingent upon the DARE-LARC1 program’s achievement of specified development and reporting milestones. As of September 30, 2023, the Company recorded a deferred grant funding liability of approximately $15.2 million in the Company's condensed consolidated balance sheets.

9. NET LOSS PER SHARE

The Company computes basic net loss per share, or EPS, using the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted EPS is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Dilutive securities include the dilutive effect of in-the-money options and warrants, which is calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option or warrant, the amount of compensation cost, if any, for future service that the Company has not yet recognized, and the amount of estimated tax benefits that would be recorded in paid-in capital, if any, when the option or warrant is exercised are assumed to be used to repurchase shares in the current period. Dilutive securities are excluded from the diluted EPS calculation if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted EPS for the period indicated because of their anti-dilutive effect:

Potentially dilutive securities	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock options	9,463,888	6,612,554	9,463,888	6,612,554
Warrants	10,006,500	1,381,015	10,006,500	1,381,015
Total	19,470,388	7,993,569	19,470,388	7,993,569

10. SUBSEQUENT EVENTS

Achievement of First Commercial Milestone Under License Agreement for XACIATO

In October 2023, the Company became entitled to receive a $1.8 million milestone payment from Organon in connection with first commercial sale in the U.S. of XACIATO in accordance with the license agreement between the Company and Organon, as amended.

ATM Sales

During November 2023, the Company sold an aggregate of 270,000 shares of common stock under its ATM equity offering program and received aggregate gross proceeds of approximately $108,000 and incurred sales agent commissions and fees of approximately $2,500 (For a discussion of the ATM program, see Note 4, Stockholders' Equity).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto for the year ended December 31, 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2022, or our 2022 10-K, filed with the Securities and Exchange Commission, or SEC, on March 30, 2023. Past operating results are not necessarily indicative of results that may occur in future periods.

The following discussion includes forward-looking statements. See "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. Risk Factors of our 2022 10-K, and in our subsequent filings with the SEC, including any discussed in Part II, Item 1A of this report under the heading "Risk Factors," which are incorporated herein by reference.

In this report, "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 presented 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.

Daré Bioscience® is a registered trademark of Daré Bioscience, Inc. and XACIATO™ is a trademark of Daré Bioscience, Inc. with registration pending. Ovaprene® is a registered trademark licensed to Daré Bioscience, Inc. All other trademarks, service marks or trade names appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, service marks or trade names is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark or trade name owners.

Business Overview

We are a 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 prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, vaginal health, reproductive health, menopause, 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 or regulatory approval, and to establish and leverage strategic collaborations to achieve commercialization. We and our wholly owned subsidiaries operate in one business segment.

The first shipment of our first product, XACIATO (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe), in connection with the first commercial sale of the product in the United States occurred in October 2023. XACIATO was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In March 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. Accordingly, our potential future revenue from the commercialization of XACIATO will consist of royalties based on net sales and milestone payments from Organon, and, for an interim period, payments from Organon for commercial supply of XACIATO.

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

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

- **Ovaprene®**, a hormone-free, monthly intravaginal contraceptive;

- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the female genitalia on demand for the treatment of female sexual arousal disorder (FSAD) and/or female sexual interest/arousal disorder (FSIAD);
- **DARE-HRT1**, an intravaginal ring designed to deliver both bio-identical estradiol and progesterone together, continuously over a 28-day period, for the treatment of moderate-to-severe vasomotor symptoms, as part of menopausal hormone therapy;
- **DARE-VVA1**, a proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe vulvovaginal atrophy; and
- **DARE-CIN**, a proprietary, fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia (CIN) and other human papillomavirus (HPV) related pathologies.

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

- **DARE-PDM1,** a proprietary hydrogel formulation of diclofenac, a nonsteroidal anti-inflammatory drug, for vaginal administration as a treatment for primary dysmenorrhea;
- **DARE-204** and **DARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively;
- **DARE-FRT1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth.

In addition, our portfolio includes five preclinical stage programs:

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **DARE-LBT**, a novel hydrogel formulation for vaginal delivery of live biotherapeutics to support vaginal health;
- **DARE-GML**, an intravaginally-delivered potential multi-target antimicrobial agent formulated with glycerol monolaurate (GML), which has shown broad antimicrobial activity, killing bacteria and viruses;
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- **DARE-PTB2**, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein.

The product candidates and potential product candidates in our portfolio will require review and approval from the FDA, or a comparable foreign regulatory authority, prior to being marketed or sold. See below and ITEM 1. "BUSINESS," in Part I of our 2022 10-K for additional information regarding our product and product candidates.

Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or regulatory approval. We expect our research and development expenses will continue to represent the majority of our operating expenses for at least the next twelve months. For the rest of 2023 and until we secure additional capital to fund our operating needs, we will focus our resources primarily on advancement of Ovaprene and Sildenafil Cream, 3.6%. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 program for the next several years, but we also expect such expenses will be supported by non-dilutive funding provided under a grant agreement we entered into in June 2021.

As discussed below, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. We are also subject to a number of other risks common to biopharmaceutical companies, including, but not limited to, dependence on key employees, reliance on third-party collaborators, service providers and suppliers, being able to develop commercially viable products in a timely and cost-effective manner, dependence on intellectual property we own or in-license and the need to protect that intellectual property and maintain those license agreements, uncertainty of market acceptance of products, uncertainty of third-party payor coverage, pricing and reimbursement for products, rapid technology change, intense competition, compliance with government regulations, product liability claims, and exposure to cybersecurity threats and incidents.

XACIATO

In October 2023, we became entitled to receive a $1.8 million milestone payment from Organon in connection with the first commercial sale in the U.S. of XACIATO in accordance with our exclusive global license agreement, as amended, and a $0.5 million payment from us to a third-party licensor became payable.

In July 2023, we entered into an amendment to our license agreement with Organon and received $1.0 million from Organon as reimbursement for registration fees paid to the FDA in connection with the new drug application (NDA) for XACIATO (known as PDUFA fees) and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, which was recognized as license fee revenue. Under our agreement with Organon, we are also entitled to receive tiered double-digit royalties based on net sales and eligible to receive up to $180.0 million in tiered commercial sales milestones and regulatory milestones.

Under the terms of our agreement with Organon, for an interim period, we will remain the holder of the FDA's marketing approval for XACIATO and be responsible for providing commercial product supply. Upon Organon's request, we will assist with the transfer of the NDA by the FDA to Organon, as well as the transfer of manufacturing responsibilities to Organon. As the current NDA holder, we will continue to be responsible for regulatory and compliance matters, though Organon is responsible for commercializing, promoting, determining pricing, and negotiating reimbursement matters related to XACIATO. Organon will purchase all of its product requirements of XACIATO from us at a transfer price equal to our manufacturing costs plus a single-digit percentage markup. We will fulfill our commercial supply obligations through the contract manufacturer that provided clinical supplies of XACIATO for our pivotal Phase 3 DARE-BVFREE clinical study of XACIATO. We will not be responsible for other costs of commercializing XACIATO.

Clinical-Stage Program Updates

Ovaprene

We anticipate subject enrollment in a single arm, open-label pivotal contraceptive efficacy study of Ovaprene to begin before the end of 2023. The multi-center, non-comparative pivotal Phase 3 clinical study will evaluate Ovaprene's effectiveness as a contraceptive device along with its safety and usability. We will target having approximately 250 women complete approximately 12 months (13 menstrual cycles) of use of Ovaprene. Based on typical dropout rates for contraceptive efficacy studies, we will seek to enroll more than double the number of subjects we target to complete 13 menstrual cycles of use. We have been working with our collaborators at the National Institutes of Health, or NIH, and at Bayer to review and implement study design considerations provided by the FDA with its Investigational Device Exemption, or IDE, approval letter, which we believe will further position the Phase 3 study to collect safety and effectiveness data to enable the preparation of, and to support the submission of, a premarket approval, or PMA, application for Ovaprene. The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. If successful, we expect the study to support a PMA application to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

The Phase 3 study will be conducted under our Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or the NICHD, part of the NIH, and within NICHD's Contraceptive Clinical Trial Network. We and NICHD will each provide medical oversight and final data review and analysis for the study and will work together to prepare the final report of the results of the study. We are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million to NICHD to be applied toward the costs of conducting the Phase 3 study, $5.0 million of which has been paid. NICHD is responsible for the other costs related to the conduct of the Phase 3 study and for managing the payment of expenses to the contract research organization for the study, the clinical sites, and other parties involved with the study. We and NICHD are in discussions regarding an amendment to the CRADA, which we expect will delay the due date of our remaining $0.5 million payment to NICHD to the first quarter of 2024. In the future, depending on the duration of the enrollment period and number of subjects enrolled in the Phase 3 study, there may be costs associated with the study that are not reflected in the current budget under the CRADA, in which case, we and NICHD would discuss the mechanism to potentially provide for additional future payments by us in support of the Phase 3 study. We do not expect any such potential additional amounts to be payable in 2023.

Sildenafil Cream, 3.6%

In June 2023, we announced topline results from our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6%, or Sildenafil Cream, in premenopausal women with FSAD, and in July and November 2023, we announced additional findings based on further analyses of data from the study. During the multi-center, double-blind, randomized, placebo-controlled study, subjects used Sildenafil Cream and placebo cream in their home setting over 12 weeks following a 4-week non-drug run-in period and a 4-week, single-blind placebo run-in period. The study was a first of its kind Phase 2b clinical study that included patient reported outcome instruments to screen for eligible women with FSAD and measure efficacy endpoints. There are no treatments approved by the FDA for FSAD, as described in the fourth edition of the Diagnostic and Statistical Manual (DSM), or for FSIAD, as described in the fifth edition of the DSM, and thus, there are no efficacy endpoints that have been previously validated in a Phase 3 pivotal study for potential treatments for FSAD or FSIAD.

We believe data from the Phase 2b RESPOND study support advancing clinical development of Sildenafil Cream into a Phase 3 pivotal study in women with FSAD and women with FSIAD whose primary complaint is arousal dysfunction using co-primary endpoints similar to those used in the Phase 2b RESPOND study to measure Sildenafil Cream's efficacy compared to placebo cream as a potential treatment for FSAD and FSIAD. Phase 3 clinical study design, including primary and secondary efficacy endpoints, study duration, timing for efficacy endpoint assessment, use of endpoints that reduce burden on study subjects (e.g., 28-day recall assessments as opposed to recall assessments within 24 hours after each sexual event), and inclusion/exclusion criteria for study subjects, will be determined following discussions with the FDA, including an end-of-phase 2 meeting with the FDA, which we expect to occur before the end of 2023.

In April 2023, we announced the initiation of subject enrollment in a Phase 1, single-dose, double-blind, placebo-controlled, 3-way crossover clinical study of Sildenafil Cream using thermography to assess the pharmacodynamic (PD) and pharmacokinetic (PK) characterization of Sildenafil Cream. We expect this study will enroll approximately 15 women and be completed in early 2024. Data from the study will expand our existing clinical and nonclinical data for Sildenafil Cream and are expected to support the ongoing development of Sildenafil Cream as a potential treatment for FSAD and/or FSIAD.

DARE-HRT1

Based on the results of our randomized, open-label, two arm, parallel group Phase 1/2 clinical study of two versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg intravaginal ring (IVR) and estradiol 160 µg/progesterone 8 mg IVR) conducted by our wholly owned subsidiary in Australia and pre-IND communications with the FDA , we plan to advance DARE-HRT1 directly into a Phase 3 clinical trial. We believe FDA approval of DARE-HRT1 for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with intact uteri is achievable via the FDA's 505(b)(2) pathway supported by a single, placebo-controlled Phase 3 clinical trial and a scientifically justified PK "bridge" (via a relative bioavailability trial) between DARE-HRT1 and the selected listed estradiol and progesterone drugs. We are conducting activities necessary to enable submission of an investigational new drug application, or IND, to the FDA for a pivotal Phase 3 clinical study of DARE-HRT1. We do not plan to conduct the Phase 3 study until after we secure additional capital.

DARE-VVA1

The results of our randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging Phase 1/2 clinical study of DARE-VVA1, conducted by our wholly owned subsidiary in Australia, support ongoing development of DARE-VVA1 as a potential hormone-free treatment for moderate-to-severe VVA. We are conducting activities to support an IND submission to the FDA and an IND-opening Phase 2 clinical study. We do not plan to conduct the Phase 2 study until after we secure additional capital.

DARE-CIN

We acquired exclusive rights to develop and commercialize in the United States an investigational, proprietary lopinavir and ritonavir combination soft gel vaginal insert, which we refer to as DARE-CIN (formerly referred to as R-131-2), for the treatment of CIN and other HPV-related pathologies. DARE-CIN was previously evaluated in a proof-of-concept clinical study and the results demonstrated its potential as a self-applied therapy for HPV infection and related cervical lesions. We are conducting limited activities to support an IND submission to the FDA to enable progression to Phase 2 clinical development in the United States.

DARE-PDM1

In February 2023, we announced the start of a Phase 1 clinical study of DARE-PDM1, which is being conducted by our wholly owned subsidiary in Australia. The DARE-PDM1 Phase 1 study, DARE-PDM1-001, is a multi-center, randomized, placebo-controlled, double-blind, three-arm parallel group study expected to enroll approximately 36 healthy, premenopausal women with primary dysmenorrhea. This study is designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac PK and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo. The study will also assess, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period will encompass approximately three menstrual cycles. We anticipate announcing topline data from the study in 2023.

DARE-204 and DARE-214

We plan to conduct Phase 1 clinical studies of DARE-204 and DARE-214 in Australia through our wholly-owned subsidiary in Australia. Additional manufacturing activities are necessary to commence the Phase 1 studies and these activities have not commenced.

Recent Events

Amendment of License Agreement for XACIATO and Achievement of First Commercial Milestone

As discussed above, in July 2023, we entered into an amendment to our exclusive global license agreement to commercialize XACIATO and received a $1.0 million payment from Organon, and in October 2023, we became entitled to receive a $1.8 million milestone payment from Organon in connection with the first commercial sale in the U.S. of XACIATO in accordance with the license agreement, as amended. In addition to the milestone payment, we are entitled to receive tiered double-digit royalties based on net sales and eligible to receive potential future milestone payments of up to $180 million. See "XACIATO," above.

Receipt of Grant Funding Installment to Support DARE-LARC1

In September 2023, we received a payment of $4.5 million as the latest installment under a grant to advance the development of our investigational contraceptive DARE-LARC1 through nonclinical proof-of-principle studies and other IND-enabling work to allow for the submission of an IND application with the FDA, approval of which will be required to commence testing in humans. Under the terms of the grant agreement, we may receive a total of up to approximately $49.0 million to support nonclinical development of DARE-LARC1. As of September 30, 2023, we had received a cumulative total of approximately $28.3 million of such total potential amount under the grant agreement. Additional payments are conditioned on the program meeting specified development and reporting milestones.

Registered Direct Offering

On August 29, 2023, we entered into a securities purchase agreement with two investors relating to the purchase and sale in a registered direct offering of an aggregate of (i) 10,000,000 shares of our common stock, and (ii) warrants to purchase an aggregate of 10,000,000 shares of our common stock. Each warrant is exercisable for one share of our common stock. The offering price was $0.70 per share of common stock and accompanying warrant. The aggregate gross proceeds to us from the offering were $7.0 million before deducting offering expenses, and net proceeds were approximately $6.8 million. The warrants are exercisable six months after issuance, have a term of five and one-half years from the date of issuance and have an exercise price of $0.77 per share, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions.

NICHD Non-Dilutive Grant Award

In July 2023, we received a notice of award of a grant from NICHD of approximately $385,000 to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds will support activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida, or USF, which are to occur over a 12-month period. We previously entered into an option agreement with the University of South Florida Research Foundation, Inc., or USFRF, a nonprofit Florida corporation that is a direct support organization of USF, pursuant to which we have an exclusive right, and not an obligation, to elect to negotiate to acquire the exclusive worldwide rights in the field of human reproduction to patents and know-how controlled by USFRF relating to the potential therapeutic whose development is being supported by the NICHD award.

Financial Overview

Revenue

To date we have generated $12.8 million in revenue, all of which is recognized as license fee revenue. Of our revenue, $10.0 million represents the upfront payment under our license agreement with Organon to commercialize XACIATO, $1.0 million represents payment under our license agreement with Organon as reimbursement for PDUFA fees and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, and $1.8 million represents the milestone payment under our license agreement with Organon in connection with the first commercial sale of XACIATO which will be recognized in the fourth quarter of 2023. In the future, we may generate revenue from royalties and commercial milestones based on the net sales of XACIATO, from product sales of other approved products, if any, and from license fees, milestone payments, and research and development payments in connection with strategic collaborations. In the future and for an interim period until the NDA for XACIATO is transferred to Organon, we may also generate revenue from commercial supply of XACIATO to Organon. Our ability to generate such revenue, with respect to XACIATO, will depend on the extent to which its commercialization is successful, and with respect to our product candidates, will depend on their successful clinical development, the receipt of regulatory approvals to market such product candidates and the eventual successful commercialization of products. If XACIATO is not commercially successful or we fail to complete the development of our product candidates in a timely manner, or to receive regulatory approval for such product candidates, our ability to generate future revenue and our results of operations would be materially adversely affected.

Research and Development Expenses

The majority of our operating expenses during a fiscal year are research and development expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. 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;

- milestone payments due to third parties under acquisition and in-licensing arrangements we incur, or the incurrence of which we deem probable; and
- internal costs associated with activities performed by our research and development organization and generally benefit multiple programs.

Investment in the development of and seeking regulatory approval for our clinical-stage and Phase 1-ready product candidates and the development of any other potential product candidates we may advance into and through clinical trials in the pursuit of regulatory approvals, will increase our research and development expenses. Activities associated with the foregoing will require a significant increase in investment in regulatory support, clinical supplies, inventory build-up related costs, and the payment of success-based milestones to licensors. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to, among other factors, license fee and/or milestone payments.

Until the first commercial sale of XACIATO, we recognized contract manufacturing expenses associated with producing commercial supplies of XACIATO and costs of regulatory affairs activities related to XACIATO as research and development expenses. Following the first commercial sale of XACIATO, and for the interim period during which we remain the holder of the FDA's marketing approval and continue to provide commercial supplies of XACIATO to Organon, those expenses will be recognized as selling, general and administrative expenses.

We recognize the Australian Research and Development Tax Incentive Program, or the Tax Incentive, as a reduction of research and development expenses. The amounts are determined based on our eligible research and development expenditures and are non-refundable, provided that in order to qualify for the Tax Incentive the filing entity must have revenue of less than AUD $20.0 million during the tax year for which a reimbursement claim is made and cannot be controlled by an income tax exempt entity. The Tax Incentive is recognized when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured or reliably estimated.

We receive funding through grants that support activities related to the development of certain of our product candidates. As we incur eligible expenses under those grants, we recognize grant funding in the statements of operations as a reduction to research and development expense (contra-research and development expense). For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies – Grant Funding, to our consolidated financial statements contained in our 2022 10-K and Note 8, Grant Awards, to our condensed consolidated financial statements contained in this report. For the three and nine months ended September 30, 2023 and 2022, we recognized contra-research and development expenses of approximately $2.6 million and $7.3 million, respectively, and $2.0 million and $4.0 million, respectively.

Conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may not obtain regulatory approval for any product candidate on a timely or cost-effective basis, or at all. 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 Fee Expenses

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

General and Administrative Expenses

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

Critical Accounting Policies and Estimates

Management's discussion and analysis of financial condition and results of operations is based on our interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. 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. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our accompanying condensed consolidated financial statements, refer to Item 7 in Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 2 to our financial statements contained in our 2022 10-K, and Note 2 to our condensed consolidated financial statements contained in this report.

Results of Operations

Comparison of Three Months Ended September 30, 2023 and 2022 (Unaudited)

The following table summarizes our condensed consolidated results of operations for the periods indicated, together with the changes in those items in terms of dollars and percentage:

	Three Months Ended September 30,		Change	
	2023	2022	$	%
Revenues:				
License fee revenue	$ 1,000,000	$ —	$ 1,000,000	100 %
Total revenue	1,000,000	—	1,000,000	100 %
Operating expenses:				
General and administrative	2,696,779	2,651,543	45,236	2 %
Research and development	6,674,636	4,462,250	2,212,386	50 %
License fee expenses	25,000	25,000	—	— %
Total operating expenses	9,396,415	7,138,793	2,257,622	32 %
Loss from operations	(8,396,415)	(7,138,793)	(1,257,622)	18 %
Other income	97,319	118,950	(21,631)	(18)%
Net loss	$ (8,299,096)	$ (7,019,843)	$ (1,279,253)	18 %
Other comprehensive loss:				
Foreign currency translation adjustments	(15,030)	(230,748)	215,718	(93)%
Comprehensive loss	$ (8,314,126)	$ (7,250,591)	$ (1,063,535)	15 %

Revenues

License fee revenue for the three months ended September 30, 2023 relates to our license agreement with Organon to commercialize XACIATO. We recognized $1.0 million in license fee revenue upon execution of the amendment to our license agreement in July 2023.

General and administrative expenses

The increase of approximately $45,000 in general and administrative expenses for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 was primarily attributable to increases in commercial-readiness expenses of approximately $0.2 million and stock-based compensation expense of approximately $41,000. These increases were partially offset by decreases in personnel costs of approximately $177,000, general corporate overhead, including rent and facilities expenses, of approximately $42,000 and professional services expense of approximately $23,000.

Research and development expenses

The increase of approximately $2.2 million in research and development expenses for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 was primarily attributable to increases in (i) expenses related to our Sildenafil Cream exploratory Phase 2b RESPOND clinical study of approximately $2.0 million, (ii) expenses related to clinical trial and manufacturing and regulatory affairs activities for Ovaprene of approximately $0.4 million, (iii) costs related to preclinical and other development expenses of approximately $0.3 million, and (iv) stock-based compensation expense of approximately $39,000. These increases were partially offset by decreases in costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $0.3 million, personnel costs of approximately $0.1 million, and expenses related to XACIATO of approximately $38,000.

License fee expenses

For each of the three months ended September 30, 2023 and September 30, 2022, we accrued $25,000 of the $100,000 annual license maintenance fee payable under our license agreement related to DARE-HRT1.

For further discussion of these license fees, see Note 3 to our condensed consolidated financial statements contained in this report.

Other income

The decrease of approximately $22,000 in other income for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 was primarily due to a decrease in interest earned on cash balances in the current period.

Comparison of Nine Months Ended September 30, 2023 and 2022 (Unaudited)

The following table summarizes our condensed consolidated results of operations for the periods indicated, together with the changes in those items in terms of dollars and percentage:

	Nine Months Ended September 30,		Change	
	2023	2022	$	%
Revenues:				
License fee revenue	$ 1,000,000	$ 10,000,000	$ (9,000,000)	(90)%
Total revenue	1,000,000	10,000,000	(9,000,000)	(90)%
Operating expenses:				
General and administrative	8,954,877	8,014,424	940,453	12 %
Research and development	17,738,543	17,065,497	673,046	4 %
License fee expenses	75,000	75,000	—	— %
Total operating expenses	26,768,420	25,154,921	1,613,499	6 %
Loss from operations	(25,768,420)	(15,154,921)	(10,613,499)	70 %
Other income	664,591	150,406	514,185	342 %
Net loss	$ (25,103,829)	$ (15,004,515)	$ (10,099,314)	67 %
Other comprehensive loss:				
Foreign currency translation adjustments	(68,186)	(375,767)	307,581	(82)%
Comprehensive loss	$ (25,172,015)	$ (15,380,282)	$ (9,791,733)	64 %

Revenues

License fee revenue relates to our license agreement with Organon to commercialize XACIATO. For the nine months ended September 30, 2023, see "*—Comparison of Three Months Ended September 30, 2023 and 2022 (Unaudited)—Revenues*," above.

For the nine months ended September 30, 2022, we recognized $10.0 million in license fee revenue related to the transfer of the license and related know-how to Organon upon effectiveness of the agreement in June 2022.

General and administrative expenses

The increase of approximately $0.9 million in general and administrative expenses for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022 was primarily attributable to (i) an increase in commercial-readiness expenses of approximately $0.4 million, (ii) a one-time fraud loss of approximately $0.2 million, net of proceeds we received under an insurance policy, related to criminal fraud commonly referred to as "business email compromise fraud" to which we were subject, (iii) an increase in stock-based compensation expense of approximately $0.2 million, and (iv) an increase in professional services expense of approximately $0.2 million. These increases were partially offset by decreases in general corporate overhead, including rent and facilities expenses, of approximately $79,000, and personnel costs of approximately $24,000.

Research and development expenses

The increase of approximately $0.7 million in research and development expenses for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022 was primarily attributable to increases in (i) costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $1.8 million, (ii) costs related to our Sildenafil Cream exploratory Phase 2b RESPOND clinical study of approximately $0.4 million, (iii) stock-based compensation expense of approximately $0.1 million, and (iv) personnel costs of approximately $89,000. These increases were partially offset by decreases in costs related to (a) clinical trial and manufacturing and regulatory affairs activities for Ovaprene of approximately $1.5 million, (b) clinical trial and manufacturing and regulatory affairs activities for XACIATO of approximately $0.2 million, and (d) rent and facilities costs of approximately $78,000.

License fee expenses

For each of the nine months ended September 30, 2023 and September 30, 2022, we accrued $75,000 of the $100,000 annual license maintenance fee payable under our license agreement related to DARE-HRT1.

For further discussion of these license fees, see Note 3 to our condensed consolidated financial statements contained in this report.

Other income

The increase of approximately $0.5 million in other income for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022 was primarily due to an increase in interest earned on cash balances in the current period.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

At September 30, 2023, our accumulated deficit was approximately $166.2 million, our cash and cash equivalents were approximately $13.9 million, and our working capital deficit was approximately $3.9 million. We incurred a loss from operations of approximately $25.1 million and had negative cash flow from operations of approximately $30.7 million during the nine months ended September 30, 2023. Substantially all of our cash and cash equivalents at September 30, 2023 represented funds received under grant agreements related to DARE-LARC1 and DARE-LBT and such funds may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. For additional information about these grant agreements, see "—Deferred Grant Funding" and "—Grant Agreements," below.

We expect to incur significant losses from operations and negative cash flows from operations for the foreseeable future as we continue to develop and seek to bring to market our product candidates. We expect our primary uses of capital 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 to third-party licensors upon the occurrence of commercial milestones for XACIATO and development milestones for our product candidates pursuant to terms of the agreements under which we acquired or in-licensed rights to those programs, 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, nature and terms of commercial collaborations we establish, and in particular, if we determine to engage in commercialization activities directly as opposed to through a third-party collaborator.

Currently, our sources of potential revenue are our license agreements relating to XACIATO and Ovaprene. In October 2023, we became entitled to receive a $1.8 million milestone payment from Organon in connection with the first commercial sale in the U.S. of XACIATO in accordance with our exclusive global license agreement, as amended, and we are eligible to receive royalty payments at rates in the tiered double-digits based on annual net sales of XACIATO. We do not expect royalty payments for 2023 net sales of XACIATO to materially impact our cash resources or requirements. In regard to our license agreement relating to the commercialization of Ovaprene in the U.S., if approved, we are not eligible to receive any additional payments from our collaborator until after we complete the planned pivotal Phase 3 clinical study of Ovaprene, which we do not expect to be completed in 2024.

We anticipate our general and administrative expenses for 2023 will exceed our general and administrative expenses for 2022 primarily due to increased commercial-readiness expenses, personnel costs and other general corporate overhead. Our general and administrative expenses for the fourth quarter of 2023 will include a $500,000 milestone payment by us under our in-license agreement for XACIATO as a result of the first commercial sale of XACIATO in the U.S.

The majority of our operating expenses during a fiscal year are research and development expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. In large part, we can control the pace of advancement of our development programs and therefore, we can control the timing of when we incur most of our research and development expenses.

We closely monitor our limited cash resources and we have implemented cost-savings measures, primarily by controlling our spend on research and development activities related to clinical-stage programs other than Ovaprene and Sildenafil Cream. Our research and development expenses for the remainder of 2023 and until we secure additional capital to fund our operating needs, will continue to be primarily associated with manufacturing activities in connection with our planned pivotal Phase 3 clinical study of Ovaprene, our ongoing Phase 1 thermography clinical study of Sildenafil Cream and other activities, including regulatory affairs activities, related to advancing Sildenafil Cream toward a Phase 3 clinical study. However, we plan to continue to advance preclinical development of DARE-LARC1 and DARE-LBT, the costs of which are being supported by grant funding.

We will need additional capital to fund our operating needs into the first quarter of 2024 and to meet our current obligations as they become due. We are in ongoing discussions with multiple potential third-party sources of additional capital, including non-dilutive sources of capital. Many aspects of our ability to obtain additional capital are not entirely within our control and there can be no assurance that we will receive additional capital when needed, on favorable terms, or at all. 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 the risk factor in Item 1A of Part II of this report titled, *We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.*

Historically, the cash used to fund our operations has come from a variety of sources and predominantly from sales of shares of our common stock. We have also received a significant amount of cash through non-dilutive grants and strategic collaborations. We will continue to evaluate and may pursue a variety of capital raising options on an on-going basis, including sales of equity (including sales of our common stock in ATM offerings), debt financings, government or other grant funding, collaborations, structured financings, and strategic alliances or other similar types of arrangements, to cover our operating expenses, and the cost of any license or other acquisition of new product candidates or technologies. 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. Our ability to raise capital through sales of our common stock will depend on a variety of factors including, among others, market conditions, the trading price and volume of our common stock, our clinical and commercial developments, and investor sentiment. In addition, macroeconomic factors and volatility in the financial market, which may be exacerbated in the short term by concerns over inflation, rising interest rates, economic recession, adverse developments affecting financial institutions or the financial services industry, impacts of the wars in Ukraine and the Middle East, strained relations between the U.S. and several other countries, and social and political discord and unrest in the U.S., among other things, may make equity or debt financings more difficult, more costly or more dilutive to our stockholders, and may increase competition for, or limit the availability of, funding from other potential third-party sources of capital, such as strategic collaborators and sources of grant funding.

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 raise capital through collaborations, structured financings, strategic alliances or other similar types of arrangements, we may be required to relinquish some or all of our rights to potential revenue or to intellectual property rights for our product candidates on terms that are not favorable to us.

We prepared the accompanying condensed 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. As discussed above, there is substantial doubt about our ability to continue as a going concern because 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 condensed consolidated financial statements. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

Deferred Grant Funding

We have received substantial funding under grant agreements related to DARE-LARC1 and DARE-LBT. Under these agreements we generally receive grant funds before we incur the eligible expenses. Funds received that have not been spent are recorded both as cash and cash equivalents and as a deferred grant funding liability in our condensed consolidated balance sheets. Our deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. At September 30, 2023, our deferred grant funding liability was approximately $15.7 million, which primarily consisted of unspent funds for the DARE-LARC1 program. The balance of our deferred grant funding liability at September 30, 2023 primarily consisted of funds for the DARE-LARC1 program that have been spent but not yet expensed in accordance with GAAP. For more information about these grant agreements, see "—Grant Agreements" below, Note 2, Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding, to our consolidated financial statements contained in our 2022 10-K and Note 8, Grant Awards—Other Non-Dilutive Grant Funding, to our condensed consolidated financial statements contained in this report.

Cash Flows

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

	Nine months ended September 30,	
	2023	2022
Net cash used in operating activities	$ (30,677,749)	$ (12,191,757)
Net cash used in investing activities	(22,099)	(60,372)
Net cash provided by financing activities	10,327,852	1,343,355
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(68,185)	(375,767)
Net decrease in cash, cash equivalents and restricted cash	$ (20,440,181)	$ (11,284,541)

Net cash used in operating activities

Cash used in operating activities for the nine months ended September 30, 2023 included the net loss of $25.1 million, decreased by non-cash stock-based compensation expense of approximately $1.9 million. Components providing operating cash were an increase in accounts payable of approximately $3.0 million, a decrease in other receivables of approximately $0.6 million, an increase in deferred revenue of approximately $0.2 million related to XACIATO commercial product supply, and a decrease in prepaid expenses of approximately $0.1 million. Components reducing operating cash were a decrease in accrued expenses of approximately $6.1 million, a decrease in deferred grant funding of approximately $2.6 million, an increase in deposits of approximately $1.8 million primarily related to deposits paid for the construction of capital equipment, an increase in other current assets of approximately $0.8 million primarily related to the financing of certain director and officer and other liability insurance premiums recorded as insurance financing payable, deferred financing costs related to our ATM sales agreement, and inventory of XACIATO commercial supply, and a one-time fraud loss of $0.2 million related to a "business email compromise fraud" to which we were subject, net of insurance reimbursement, which was recognized in general and administrative expenses.

Cash used in operating activities for the nine months ended September 30, 2022 included the net loss of $15.0 million, decreased by non-cash stock-based compensation expense of approximately $1.6 million. Components providing operating cash were an increase in deferred grant funding of approximately $4.3 million, an increase in accounts payable of approximately $1.4 million, and an increase in accrued expenses of approximately $1.0 million. Components reducing operating cash were an increase in prepaid expenses of approximately $4.4 million and an increase in other receivables of approximately $1.1 million.

Net cash used in investing activities

Cash used in investing activities for the nine months ended September 30, 2023 and September 30, 2022 was de minimis.

Net cash provided by financing activities

Cash provided by financing activities for the nine months ended September 30, 2023 of approximately $10.3 million primarily consisted of proceeds from (i) the sale of our common stock and warrants in the registered direct offering completed in September 2023, (ii) sales of our common stock under our ATM sales agreement, (iii) the exercise of warrants, and (iv) the financing of certain director and officer and other liability insurance premiums.

Cash provided by financing activities for the nine months ended September 30, 2022 of approximately $1.3 million primarily consisted of proceeds from sales of our common stock under our ATM sales agreement.

License and Royalty Agreements

We agreed to make royalty and milestone payments under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream, and under other agreements related to our other clinical and preclinical candidates. During the remainder of 2023, based on our current expectations regarding the development of our product candidates and sales of XACIATO, we expect to pay approximately $0.6 million in license fee expense and milestone payments under the license and development agreements, which is significantly less than our previously reported expected amount, primarily due to lesser anticipated royalty payments we may owe with respect to sales of XACIATO resulting from the delay of its commercial launch from earlier expectations and lesser anticipated milestone payments with respect to milestone events for certain product candidates no longer expected to occur in 2023. For further discussion of these potential payments, see Note 3 to our condensed consolidated financial statements contained in this report.

Grant Agreements

We have received substantial funding under grant agreements related to DARE-LARC1 and DARE-LBT. In September 2023, following an assessment of our activities and the milestones we achieved to date, we received $4.5 million as the latest installment under the grant agreement to advance the preclinical development of DARE-LARC1. Grant funds under these agreements generally are received before we incur the eligible expenses. Unspent grant funds are recorded as deferred grant funding liability in our condensed consolidated balance sheets and our deferred grant funding liability as of September 30, 2023 primarily consisted of unspent grant funds for the DARE-LARC1 program. For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies —Grant Funding, to our consolidated financial statements contained in our 2022 10-K and Note 8, Grant Awards—Other Non-Dilutive Grant Funding, to our condensed consolidated financial statements contained in this report.

Other Contractual Obligations

We enter into contracts in the normal course of business with various third parties for research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and we do not believe that our non-cancelable obligations under these agreements are material.

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 3. 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 4. 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.

Based on an evaluation performed 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, 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 September 30, 2023 at the reasonable assurance level.

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 fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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, diversion 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 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described in our 2022 10-K, in addition to other information in this report, before investing in our common stock. The occurrence of any of these risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. Except as discussed below, there have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in our 2022 10-K.

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

We have a history of losses from operations, we expect negative cash flows from our operations to continue for the foreseeable future, and 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 as we seek to potentially acquire or license and develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2022 and September 30, 2023 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. At September 30, 2023, our accumulated deficit was approximately $166.2 million, our cash and cash equivalents were approximately $13.9 million, our deferred grant funding liabilities under our grant agreements related to DARE-LARC1 and DARE-LBT were approximately $15.7 million, and we had a working capital deficit of approximately $3.9 million. Substantially all of our cash and cash equivalents at September 30, 2023 represented funds received under such grant agreements and such funds may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. We will require additional capital to fund our operating needs into the first quarter of 2024 and to meet our current obligations as they become due. Advancing our investigational women's health products through clinical development and pursuing regulatory approval and commercialization will require substantial additional investment. We will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. The amount and timing of our capital needs have and will continue to depend highly on many factors, as discussed further below as well as under "ITEM 2. MANAGEMENT'S DISCUSSION OF AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS—Liquidity and Capital Resources—Plan of Operations and Future Funding Requirements" in Part I of this report.

Our management has devoted, and may continue to devote, significant time and we may incur substantial costs in pursuing, evaluating and negotiating potential capital-raising transactions and those efforts may not prove successful on a timely basis, or at all. If we cannot raise adequate additional capital when needed, we may be forced to reduce, or even terminate our operations. We may delay, scale back or eliminate one or more of our product development programs; delay, limit or terminate activities in support of our third-party collaborator’s commercialization of XACIATO in the U.S.; relinquish rights under our license agreements with third parties relating to our product and product candidates; forgo opportunities to expand our product portfolio; take other measures to reduce our expenses; reorganize or merge with another entity; or file for bankruptcy or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and our stockholders may lose all or part of their investment in our common stock.

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

- the product development programs we choose to pursue;

- the cost and pace of preclinical and clinical development;
- the results of preclinical activities and clinical trials;
- the cost and timing of obtaining clinical supplies of product candidates and commercial supplies of products;
- the cost and timing of regulatory submissions and decisions by the FDA and other regulatory authorities on our applications to commence and advance clinical development of and to market our product candidates;
- the amount and timing of payments to third parties required under acquisition, in-license and other agreements relating our rights to develop and commercialize our product and product candidates;
- the cost and timing of commercialization activities we undertake or engage third parties to undertake for any approved product;
- the amount and timing of future royalty, milestone or other payments, if any, we receive under our commercial collaboration agreements for XACIATO and Ovaprene;
- our ability to maintain, and establish new, strategic collaborations relating to the development and/or commercialization of our product and product candidates;
- the extent to which we acquire, in-license, or otherwise invest in new product candidates or technologies and the terms of any such transaction; and
- the cost and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights.

Should we add product candidates to our portfolio, should our existing product candidates require testing or other capital-intensive development activities that we do not anticipate, should the duration of our clinical trials be longer than anticipated, should manufacturing and supply be disrupted, or should regulatory approvals be delayed, our cash resources will be further strained. Should our product development efforts succeed, we will need to develop a commercialization plan for each product, which may also require significant resources to create and implement. In addition, the terms of any collaboration agreements for development and/or commercialization of our product and product candidates may significantly impact our need for additional capital. Because of these uncertainties and the other risks and uncertainties discussed in the “Risk Factors” sections of this report and our 2022 10-K, we cannot reasonably estimate the amount funding necessary to successfully complete development of and seek regulatory approval for our product candidates or to commercialize any approved products. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our planned operations.

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

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

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

Our common stock is listed on the Nasdaq Capital Market. As previously reported, on July 19, 2023, we received a letter from the Listing Qualifications Department (the "Nasdaq Staff") of the Nasdaq Stock Market ("Nasdaq") notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"), and that we have initial period of 180 calendar days, or until January 16, 2024 (the "Compliance Date"), to regain compliance. We will regain compliance if the closing bid price of our common stock is at least $1.00 for a minimum of 10 consecutive business days during such 180-day period, unless the Nasdaq Staff exercises its discretion to extend such 10-day period.

If we have not regained compliance by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify for this additional compliance period, we would have to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the Minimum Bid Price Requirement, including having stockholders' equity of at least $5.0 million under the "Equity Standard" or of at least $4.0 million under the "Market Value of Listed Securities Standard" or "Net Income Standard," and we would need to provide written notice of our intention to cure the minimum bid price deficiency during the additional compliance period, by effecting a reverse stock split, if necessary. Our stockholders' equity at September 30, 2023 was negative $2.3 million and, as a result, we do not currently meet all the initial listing standards for The Nasdaq Capital Market. If we are not granted the additional compliance period for any reason, the Nasdaq Staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the Nasdaq Staff's delisting determination to a Nasdaq Hearing Panel.

There can be no assurance we will regain compliance with the Minimum Bid Price Requirement or continue to satisfy the other continued listing requirements of The Nasdaq Capital Market. The 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.

An extended curtailment or halt of operations at the FDA, NIH, SEC and other government agencies, including due to a U.S. federal government shutdown, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and our ability to raise additional capital.

Twice in the past decade, the previous appropriations legislation deadline was reached and Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U.S. government shutdowns that caused federal agencies to halt non-essential operations. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. If lawmakers cannot pass a continuing resolution or a new federal budget by November 17, 2023, another federal government shutdown would begin. A federal government shutdown could prevent staff at federal agencies from performing key functions that may adversely affect our business. For example, disruptions at the FDA may delay meetings and other communications with agency staff necessary to progress development of our product candidates and may slow the time necessary for acceptance, review and approval of applications to commence clinical studies or to market a new product in the U.S. By way of further example, disruptions at the NIH, including its various institutes and centers, such as NICHD, could delay processing of new grant awards to fund research and development of potential new therapies or the disrupt staff's work and other activities or funding under active grant/cooperative agreements. Based on recent discussions with NICHD staff, we currently do not expect a government shutdown to materially affect the commencement or conduct of our planned Phase 3 clinical study of Ovaprene because funding for planned costs into the third quarter of 2024, including the $5.0 million we previously paid under the CRADA toward the cost of the study, has been allocated and will be available. If a prolonged government shutdown occurs, however, it could adversely impact the ability of NICHD to carry out its responsibilities under our CRADA, including funding its share of the costs of the study, which could have a material adverse impact on our business. In addition, a government shutdown could prevent SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. While we currently have an effective shelf registration statement on Form S-3, if a federal government shutdown halts non-essential SEC operations for an extended period, it may negatively impact our ability to raise additional capital through registered offerings of our securities in the future. If a prolonged U.S. government shutdown or other event or condition occurs that prevents the FDA, NIH, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, which could have a material adverse effect on our business.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities

(a) None.
(b) None.
(c) None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.
(b) None.
(c) Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item in this report.

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
4.1	Form of common stock purchase warrants issued on September 1, 2023	8-K	001-36395	8/30/2023	4.1	
10.1	Form of Securities Purchase Agreement dated as of August 29, 2023, between Daré Bioscience, Inc. and each purchaser identified on the signature pages thereto	8-K	001-36395	8/30/2023	10.1	
10.2+	First Amendment to License Agreement by and between Organon International GmbH and Daré Bioscience, Inc., entered into as of July 4, 2023					X
10.3*	Daré Bioscience, Inc. Performance Bonus Plan, as amended					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					#
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					#
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101)					X

\+ Portions of this exhibit have been redacted in accordance with Item 601(b)(10)(iv) of Regulation S-K. The omitted information is not material and is information that the registrant customarily and actually treats as private or confidential.

*	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.

Signatures

Pursuant to the requirements 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.

Date: November 9, 2023

By: /s/ Sabrina Martucci Johnson
Sabrina Martucci Johnson
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2023

By: /s/ Lisa Walters-Hoffert
Lisa Walters-Hoffert
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

FIRST AMENDMENT
TO
LICENSE AGREEMENT

by and between

ORGANON INTERNATIONAL GMBH

and

DARÉ BIOSCIENCE, INC.

FIRST AMENDMENT TO LICENSE AGREEMENT

This First Amendment to License Agreement (this "**First Amendment**") is entered into as of July 4, 2023 (the "**Execution Date**") by and between Organon International GmbH, a limited liability company organized and existing under the laws of Switzerland ("**Organon**") and Daré Bioscience, Inc., a corporation organized and existing under the laws of Delaware ("**Daré**") (each a "**Party**" and collectively the "**Parties**"). Capitalized terms not defined herein are defined in the License Agreement.

RECITALS

Whereas, Organon and Daré entered into that certain Exclusive License Agreement dated as of March 31, 2022 (the "**License Agreement**") pursuant to which Daré grants to Organon and its affiliates an exclusive license to Develop, Commercialize and otherwise Exploit Licensed Product;

Whereas, Organon LLC and Daré entered into that certain Supply and Distribution Agreement, dated July 12, 2022 (the "**Supply Agreement**") to establish certain manufacturing and supply relationships between the Parties with respect to the Supplied Product (as such term is defined in the Supply Agreement);

Whereas, Daré owns and holds Daré Marketing Authorizations and Daré Regulatory Materials, but pursuant to Section 2.1 of the License Agreement has provided a present tense assignment of the Daré Marketing Authorizations and Daré Regulatory Materials to Organon, upon Organon's request;

Whereas, under the License Agreement, as the owner of the NDA for the Supplied Product, Daré is responsible to pay registration fees, including the annual Prescription Drug User Fee Act ("**PDUFA**") fees, for the Supplied Product imposed by the FDA;

Whereas, [***].

Whereas, [***];

Whereas, the Parties wish to clarify certain regulatory obligations related to the [***] notifications and submissions to Regulatory Authority, Recall of the Supplied Product (as such terms are defined in the Supply Agreement), and use and access to data and materials from developmental work and validation; and

Whereas, in order to continue to advance the development and commercialization of the Supplied Product, the Parties are executing this First Amendment to supplement and amend the terms of the License Agreement on the terms and subject to the conditions set forth herein.

Now Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Organon and Daré hereby agree as follows:

1. PURPOSE AND EFFECT OF THIS FIRST AMENDMENT

This First Amendment is intended to supplement and amend the License Agreement and Supply Agreement with respect to (i) the provision of additional funds in the amount of One Million Dollars ($1,000,000) from Organon to Daré to reimburse Daré for PDUFA fees and other manufacturing expenses and to permit Dare to continue to advance the development and commercialization of the Supplied Product (such amount, the "**Additional Consideration**") and (ii) amend and restate the amount of the First Commercial Sale Milestone as set forth below. Except as otherwise expressly provided herein, the

terms and conditions of the License Agreement and the Supply Agreement shall remain unchanged and in full force and effect.

2. REPRESENTATIONS AND WARRANTIES AND COVENANTS

Daré represents and warrants to Organon that as of the Execution Date:

(a) Daré has provided to Organon a true, correct and complete copy of the fully executed Supply and Manufacturing Agreement [***], including any and all amendments, restatements, project agreements, side letters, and other modifications thereto (the "[***] **Supply Agreement**"), as such [***] Supply Agreement is in effect as of the Execution Date; and

(b) [***].

Daré hereby covenants that Daré will (a) use Commercially Reasonable Efforts keep Organon informed of all material actions taken or intended to be taken in connection with the [***] Supply Agreement, (b) [***], and (c) [***] (including the Daré's satisfaction of the Daré's obligations under Section 2.1.1 of the License Agreement).

3. AMENDMENT OF FIRST COMMERCIAL SALE MILESTONE; PAYMENT OF ADDITIONAL CONSIDERATION

In consideration of the representations, warranties and covenants of Dare set forth herein and the release by Daré and each other Releasor as set forth and defined in Section 4 below and for good and valuable consideration, the Parties hereby agree that:

(a) Section 6.2.1 of the License Agreement is hereby deleted in its entirety and is replaced with the following provision:

"6.2.1 **First Commercial Sale Milestone**. Organon shall pay to Daré within [***] of the first shipment of Licensed Product from the contract manufacturer in connection with the First Commercial Sale One Million Eight Hundred Thousand Dollars ($1,800,000) for the First Commercial Sale in the United States of a Licensed Product."

And

(b) Notwithstanding that neither the License Agreement nor the Supply Agreement require that Organon or any of its Affiliates [***] upon the terms and conditions contained herein, within [***], Organon shall pay to Daré the Additional Consideration.

4. RELEASE

Effective for all purposes (except as expressly limited below) as of the Execution Date, Daré acknowledges and agrees on behalf of itself and on behalf of each of its past, present or future agents, trustees, directors, managers, officers, affiliates, subsidiaries, representatives, successors, and assigns (Daré and each such other person or entity, a "**Releasor**"), that:

a. Each Releasor, hereby irrevocably and unconditionally releases Organon and each of its past, present or future agents, trustees, directors, managers, officers, affiliates, subsidiaries, representatives, successors, and assigns (each, a "**Releasee**") from any and all charges, complaints, claims, liabilities, obligations, promises, agreements, controversies, damages or causes of action, suits, rights, demands, costs, losses, debts and expenses ***] of any nature

whatsoever, [***] (collectively, "**Losses**"), arising out of: (i) [***], (ii) [***]; (iii) [***], (iv) any other costs and expenses related to the Supplied Product or the Supply Agreement incurred by or on behalf of Dare as of the Execution Date, and (v) the License Agreement (as amended hereby) or the Supply Agreement for any actual or alleged failure (as of the date hereof) of Organon to perform, or of any breach by Organon under, each of the License Agreement (including, without limitation, under Section 3.4.1 of the License Agreement) and the Supply Agreement (each of clauses (i) through (v), a "**Claim**" and collectively referred to herein as, "**Claims**"). Each Releasor also releases Organon and its Releasees from any costs incurred by Daré [***], unless such costs are incurred after the Execution Date of this First Amendment and satisfy the requirements for Organon to reimburse the costs under the Supply Agreement, including the requirement that Organon approve such costs in advance.

b. Daré acknowledges that it is familiar with and understands Section 1542 of the Civil Code of the State of California ("Section 1542"), which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

Effective for all purposes each Releasor, hereby expressly waives and relinquishes any rights and benefits that such Releasor may have under Section 1542 or any similar statute or common law principle of any jurisdiction with respect to the Claims released under this Section 4.

c. Daré acknowledges that it or other Releasors may hereafter discover facts in addition to or different from those that it or any other Releasor now knows or believes to be true with respect to the subject matter of this release, but it is Daré's intention, including on behalf of each Releasor, to fully and finally and forever settle and release any and all Claims that do now exist, may exist or heretofore have existed between Releasor and any of the Releasees with respect to the subject matter of this release. In furtherance of this intention, the releases contained herein shall be and remain in effect as full and complete releases of the Claims, notwithstanding the discovery or existence of any such additional or different facts.

5. REGULATORY OBLIGATIONS

a. Daré will comply with GMP, Applicable Laws and the Quality Agreement (as defined in the Supply Agreement) [***].

b. Daré agrees to not submit any registration or filing related to the Licensed Product, [***], to any Regulatory Authority unless such submission is authorized by Organon.

6. USE AND ACCESS RIGHTS TO DEVELOPMENT WORK

Daré shall provide Organon access and use rights for any work product and materials resulting from any additional activities and services for which Organon paid costs pursuant to Section 5.1 of the Supply Agreement [***].

7. ENTIRE AGREEMENT; CONSTRUCTION

This First Amendment contains the entire understanding of the Parties with respect to subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and

commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this First Amendment, provided that the License Agreement (as amended) and Supply Agreement shall remain in full force and effect. This First Amendment may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

8. MISCELLANEOUS

a. The provisions of Article 5 (Confidentiality and Publicity), Section 6.7 (Income Tax Withholding) and Article 12 (Miscellaneous) of the License Agreement, other than Section 12.8 of the License Agreement, shall apply to this First Amendment as if set forth in full in this First Amendment. If the License Agreement is terminated, this First Amendment shall also be automatically terminated and shall be of no further force or effect. In connection with any breach of this First Amendment, neither party shall be liable in contract, tort, negligence, breach of statutory duty, or otherwise for any special, punitive, or consequential damages or for loss of profits suffered by the other party (or its Affiliates or (sub)licensees), regardless of any notice of the possibility of such losses.

b. From and after the Execution Date, each reference in the License Agreement to "hereunder," "hereof," "this Agreement" or words of like import and each reference in the Supply Agreement to "License Agreement," "thereunder," "thereof" or words of like import shall, unless the context otherwise requires, mean and be a reference to the License Agreement as amended by this First Amendment or the Supply Agreement, as applicable.

c. Each of the License Agreement and the Supply Agreement, and the obligations of Daré under the License Agreement and the Supply Agreement, are hereby ratified and confirmed and shall remain in full force and effect according to their terms.
`

d. Each Party (i) acknowledges and consents to all of the terms and conditions of this First Amendment, (ii) affirms all of its obligations under the License Agreement (as hereby amended) and the Supply Agreement, and (iii) agrees that this First Amendment and all documents executed in connection herewith do not operate to reduce or discharge its obligations under the License Agreement (as hereby amended) or the Supply Agreement.

e. The execution, delivery and effectiveness of this First Amendment shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of either Party under the License Agreement or the Supply Agreement, nor constitute a waiver of any provision of any of the License Agreement or the Supply Agreement.

[**SIGNATURES ON FOLLOWING PAGE**]

IN WITNESS WHEREOF, the Parties have executed this First Amendment by their duly authorized representatives as of the Execution Date.

ORGANON INTERNATIONAL GMBH	DARÉ BIOSCIENCE, INC.
BY: /s/ Matthew M. Walsh	BY:/s/ Sabrina Johnson
NAME: Matthew M. Walsh	NAME: Sabrina Johnson
TITLE: Chief Financial Officer	TITLE: CEO

Attachment omitted in accordance with Item 601(a)(5) of Regulation S-K:

Exhibit A - copy of invoice

DARÉ BIOSCIENCE, INC.

PERFORMANCE BONUS PLAN

1. Purpose

This Performance Bonus Plan (this "**Plan**") is intended to provide an incentive for superior work and to motivate eligible employees of Daré Bioscience, Inc. (the "**Company**") and its subsidiaries toward even higher achievement and business results, to tie their goals and interests to those of the Company and its stockholders, and to enable the Company to attract and retain highly qualified employees. This Plan is for the benefit of Participants (as defined below).

2. Participants

From time to time, the Compensation Committee (the "**Compensation Committee**") of the Board of Directors (the "**Board**") of the Company may select certain employees of the Company or its subsidiaries to be eligible to receive cash bonuses under this Plan with respect to a particular performance period (the employees so selected, "**Participants**"). Participation in this Plan does not change the "at will" nature of a Participant's employment with the Company or any of its subsidiaries.

3. Administration

The Compensation Committee shall have the sole discretion and authority to administer and interpret this Plan. Subject to applicable law, rules and regulations, from time to time, the Compensation Committee may request that the Board exercise any of the discretion or authority of the Compensation Committee under this Plan.

4. Bonus Determinations

(a) Performance Goals. A Participant may receive a cash bonus payment under this Plan based upon the achievement of one or more performance objectives that are established by the Compensation Committee and relate to financial and operational metrics with respect to the Company or any of its subsidiaries (the "**Performance Goals**"), including the following: developmental, clinical or regulatory milestones; clinical trial results; business development and financing milestones; acquisitions or strategic transactions; revenue; expense levels; total shareholder return; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of the Company's common stock; economic value-added; sales or revenue milestones; operating income (loss); cash flow (including, but not limited to, operating cash flow and free cash flow); return on capital, assets, equity, or investment; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; publications; reimbursement decisions; working capital; earnings (loss) per share of the Company's common stock; sales or market share; number of customers or units of products sold; and operating income and/or net annual recurring revenue, any of which may be (A) measured in absolute terms or compared to any incremental increase, (B) measured in terms of growth, (C) compared to another company or companies or to results of a peer group, (D) measured against the market as a whole and/or as compared to applicable market indices and/or (E) measured on a pre-tax or post-tax basis (if applicable). Further, any Performance Goals may be used to measure the performance of the Company as a whole or a business unit or other segment of the Company, or one or more product lines or specific markets. The Performance Goals may differ from Participant to Participant.

(b) Calculation of Performance Goals. At the beginning of each applicable performance period, the Compensation Committee will determine whether any significant element(s) will be included in or excluded from the calculation of any Performance Goal with respect to any Participant. In all other respects, Performance Goals will be calculated in accordance with the Company's financial statements, generally accepted accounting principles, or under a methodology established by the Compensation Committee and which is consistently applied with respect to a Performance Goal in the relevant performance period. The Compensation Committee shall determine when a performance period begins and ends.

(c) Target; Minimum; Maximum. Each Performance Goal will have a "target" (100 percent attainment of the Performance Goal) and may also have a "minimum" hurdle and/or a "maximum" amount.

(d) Bonus Requirements; Individual Goals. Except as otherwise set forth in this Section 4(d): (i) any bonuses paid to Participants under this Plan shall be based upon objectively determinable bonus formulas that tie such bonuses to one or more performance targets relating to the Performance Goals (certain Performance Goals may be given more weight than others), (ii) bonus formulas for Participants shall be adopted in each performance period by the Compensation Committee and communicated to each Participant and (iii) no bonuses shall be paid to Participants unless and until the Compensation Committee makes a determination with respect to the attainment of the performance objectives relating to the Performance Goals. Notwithstanding the foregoing, the Compensation Committee may adjust bonuses payable under this Plan based on achievement of one or more individual performance objectives or pay bonuses (including, without limitation, discretionary bonuses) to Participants under this Plan based on individual performance goals and/or upon such other terms and conditions as the Compensation Committee may in its discretion determine.

(e) Individual Target Bonuses. The Compensation Committee shall establish a target bonus opportunity for each Participant for each performance period (the "Target Bonus"). For each Participant, the Compensation Committee shall have the authority to apportion the Target Bonus so that a portion of it is tied to attainment of Performance Goals and a portion of it is tied to attainment of individual performance objectives.

(f) Employment Requirement. Subject to any additional terms contained in a written agreement between the Participant and the Company or any of its subsidiaries, the payment of a bonus to a Participant under this Plan with respect to a performance period is conditioned on the Participant's employment by the Company or its subsidiary on the bonus payment date. If a Participant was not employed by the Company or its subsidiary for an entire performance period, the Compensation Committee may pro rate the bonus based on the number of days employed during such period, the number of full calendar months employed during such period or any other reasonable method approved by the Compensation Committee.

5. Timing of Payment

(a) With respect to Performance Goals established and measured on a basis more frequently than annually (e.g., quarterly or semi-annually), the Performance Goals will be measured as of the end of each performance period and after such period has ended; provided, that with respect to any Performance Goals that are dependent on financial metrics as reported in the Company's periodic reports filed with the U.S. Securities and Exchange Commission for any particular period, such Performance Goals will be measured after the applicable periodic reports have been so filed. If the Performance Goals and/or individual goals for a performance period are met, payments will be made as soon as practicable following the end of such performance

period, but not later than 74 days after the end of the fiscal year in which such performance period ends.

(b) With respect to Performance Goals established and measured on an annual or multi-year basis, Performance Goals will be measured as of the end of each such performance period (e.g., the end of each fiscal year) and after such period has ended; provided, that with respect to any Performance Goals that are dependent on financial metrics as reported in the Company's periodic reports filed with the U.S. Securities and Exchange Commission for any particular period, such Performance Goals will be measured after the applicable periodic reports have been so filed. If the Performance Goals and/ or individual goals for any performance period are met, bonus payments will be made as soon as practicable, but not later than 74 days after the end of the relevant fiscal year.

(c) For the avoidance of doubt, bonuses earned at any time in a fiscal year must be paid no later than 74 days after the last day of such fiscal year.

6. Amendment and Termination

The Company, acting through the Board, reserves the right to, and may, amend or terminate this Plan at any time in its sole discretion.

Exhibit 31.1

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ Sabrina Martucci Johnson
Sabrina Martucci Johnson
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Lisa Walters-Hoffert, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ Lisa Walters-Hoffert
Lisa Walters-Hoffert
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2023

/s/ Sabrina Martucci Johnson

Sabrina Martucci Johnson
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2023

/s/ Lisa Walters-Hoffert

Lisa Walters-Hoffert
Chief Financial Officer
(principal financial officer)