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 March 31, 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 May 10, 2023, 86,284,827 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, 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™ 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 pre-clinical 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 pre-clinical development of DARE-LARC1;*
- *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

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 19,829,404	$ 34,669,605
Other receivables	2,398,708	1,703,160
Prepaid expenses	7,082,452	6,665,988
Other current assets	201,385	—
Total current assets	29,511,949	43,038,753
Property and equipment, net	55,400	64,908
Other non-current assets	799,327	722,722
Total assets	$ 30,366,676	$ 43,826,383
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,695,612	$ 2,027,953
Accrued expenses	5,480,203	10,894,016
Deferred grant funding	15,826,369	18,303,567
Current portion of lease liabilities	335,764	398,391
Total current liabilities	24,337,948	31,623,927
Deferred license revenue	1,000,000	1,000,000
Lease liabilities long-term	57,128	90,346
Total liabilities	25,395,076	32,714,273
Commitments and contingencies (Note 7)		
Stockholders' equity		
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; 86,178,996 and 84,825,481 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	8,618	8,482
Accumulated other comprehensive loss	(373,316)	(351,311)
Additional paid-in capital	154,453,439	152,529,579
Accumulated deficit	(149,117,141)	(141,074,640)
Total stockholders' equity	4,971,600	11,112,110
Total liabilities and stockholders' equity	$ 30,366,676	$ 43,826,383

See accompanying notes.

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

	Three months ended March 31,	
	2023	**2022**
Operating expenses		
General and administrative	$ 3,337,426	$ 2,569,987
Research and development	5,020,223	5,805,462
License fee expense	25,000	25,000
Total operating expenses	8,382,649	8,400,449
Loss from operations	(8,382,649)	(8,400,449)
Other income	340,148	1,779
Net loss	$ (8,042,501)	$ (8,398,670)
Net loss to common shareholders	$ (8,042,501)	$ (8,398,670)
Foreign currency translation adjustments	(22,005)	(9,150)
Comprehensive loss	$ (8,064,506)	$ (8,407,820)
Loss per common share - basic and diluted	$ (0.09)	$ (0.10)
Weighted average number of shares outstanding:		
Basic and diluted	85,517,540	83,944,119

See accompanying notes.

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

Three Months Ended March 31, 2023

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity
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**

Three Months Ended March 31, 2022

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity
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**

See accompanying notes.

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

	Three months ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (8,042,501)	$ (8,398,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	9,508	5,227
Stock-based compensation	624,621	532,409
Non-cash operating lease cost	(5,906)	(9,758)
Changes in operating assets and liabilities:		
Other receivables	(695,548)	(584,534)
Prepaid expenses	(416,464)	(4,293,814)
Other current assets	(201,385)	—
Other non-current assets	(166,545)	87,891
Accounts payable	667,661	727,783
Accrued expenses	(5,413,814)	401,613
Deferred grant funding	(2,477,198)	(811,620)
Net cash used in operating activities	(16,117,571)	(12,343,473)
Cash flows from investing activities		
Purchases of property and equipment	—	(4,553)
Net cash used in investing activities	—	(4,553)
Cash flows from financing activities		
Proceeds from the exercise of common stock warrants	1,299,375	—
Net cash provided by financing activities	1,299,375	—
Effect of exchange rate changes on cash and cash equivalents	(22,005)	(9,150)
Net change in cash and cash equivalents	(14,840,201)	(12,357,176)
Cash and cash equivalents, beginning of period	34,669,605	51,674,087
Cash and cash equivalents, end of period	$ 19,829,404	$ 39,316,911
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities, net	$ —	$ 1,043,590

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 Company's product, XACIATO™ (clindamycin phosphate vaginal gel, 2%), was approved by the FDA in December 2021, as a single-dose prescription medication for the treatment of bacterial vaginosis in female patients 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. That agreement became effective in June 2022, and in July 2022, the Company received the $10.0 million non-refundable and non-creditable payment due upon the effectiveness of the agreement.

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 and Cash Equivalents

The Company considers cash and all highly liquid investments with an original maturity of three months or less to be cash and cash equivalents. The Company's wholly owned subsidiary, Dare MB Inc., has a $35,000 letter of credit related to the lease of real property that serves as security for future default of lease payments. The letter of credit is collateralized by cash which is unavailable for withdrawal or for usage for general obligations and is included in cash and cash equivalents on the Company's consolidated balance 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 March 31, 2023, the Company had an accumulated deficit of approximately $149.1 million, cash and cash equivalents of approximately $19.8 million, a deferred grant funding liability of $15.8 million and working capital of approximately $5.2 million. The amount of the deferred grant funding liability is included in the Company's cash and cash equivalents, and represents grant funds received 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 three months ended March 31, 2023, the Company incurred a net loss of approximately $8.0 million and had negative cash flow from operations of approximately $16.1 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 March 31, 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 March 31, 2023 or December 31, 2022.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at March 31, 2023				
Current assets:				
Cash equivalents [1]	$ 18,380,017	$ —	$ —	$ 18,380,017
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 March 31, 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 $10.0 million in license fee revenue, all of which represents the upfront payment due under its license agreement for XACIATO.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, 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 March 31, 2023, the Company has not recognized any royalty revenue.

Product Supply. Arrangements that include a promise for future supply of product for commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company evaluates whether it is the principal or agent in the arrangement. The evaluation is based on the degree the Company controls the specified product at any time before transfer to the customer. Revenues are recognized on a gross basis if the Company is in the capacity of principal and on a net basis if the Company is in the capacity of an agent. As of March 31, 2023, the Company has not recognized any revenue associated with product supply arrangements.

Milestones. 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. 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 March 31, 2023, the Company has not recognized any milestone revenue.

Bayer License. In January 2020, the Company entered into a license agreement with Bayer HealthCare LLC, or Bayer, regarding the further development and commercialization of Ovaprene in the U.S. Upon execution of the agreement, the Company received a $1.0 million upfront non-refundable license fee payment from Bayer. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $20.0 million. The Company concluded that there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (1) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (2) the termination of the agreement. As of March 31, 2023, neither of the foregoing had occurred. The $1.0 million payment is recorded as deferred license revenue in the Company's consolidated balance sheets at March 31, 2023 and December 31, 2022.

The Company will also be entitled to receive (a) milestone payments totaling up to $310.0 million related to the commercial sales of Ovaprene, if all such milestones are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Potential future payments for variable consideration, such as commercial milestones, will be recognized when it is probable that, if recorded, a significant reversal will not take place. Potential future royalty payments will be recorded as revenue when the associated sales occur. (See Note 3, Strategic Agreements.)

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 the $10.0 million non-refundable and non-creditable payment, which was recorded as license fee revenue.

Under the terms of the license agreement, the Company is entitled to receive tiered double-digit royalties based on net sales and up to $182.5 million in milestone payments as follows: $2.5 million following 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.

The Company concluded at the inception of the agreement 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 March 31, 2023, no adjustments were made to the transaction price.

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 either 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 or the termination of the agreement. As of March 31, 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 March 31, 2023 and December 31, 2022.

The Company is 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

Hennepin License Agreement

In August 2022, the Company entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which the Company acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. As a result of this license, the Company commenced its DARE-GML. 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 and sales milestone payments of up to $6.25 million in the aggregate upon achieving certain development and regulatory milestones, and of up to $45.0 million in the aggregate upon achieving certain commercial sales milestones for each product covered by the licenses granted under the agreement, which may be paid, in 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 March 31, 2023, no payments have been made under this agreement.

MBI Acquisition

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

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

In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events. 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 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 March 31, 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 achieving certain clinical development and regulatory milestones by licensed products, and (b) up to $47.0 million in the aggregate upon achieving 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 achieving 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. (formerly known as Juniper Pharmaceuticals, Inc., and which the Company refers to as Catalent), under which Catalent granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, to make, have made, use, have used, sell, have sold, import and have imported products and processes, and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Catalent to make, have made, use, have used, sell, have sold, import and have imported products and processes. The Company is entitled to sublicense the rights granted to it under this agreement.

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 March 31, 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. (formerly known as Orbis Biosciences, Inc., and which the Company refers to as Adare), for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which 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, 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 achieving certain clinical and regulatory milestones in the U.S. and worldwide, and up to $100.0 million in the aggregate upon achieving certain commercial sales milestones. If the Company enters into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST. 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.

March 2023 ATM Sales Agreement

In March 2023, the Company entered into a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, and Cantor Fitzgerald & Co., or Cantor, to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program under which Stifel and Cantor act as the Company's agent. The Company agreed to pay a commission equal to 3% of the gross proceeds of any common stock sold under the agreement or such lower amount as the Company and Stifel and Cantor agree, plus certain legal expenses. 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 three months ended March 31, 2023, the Company sold no shares of common stock under this agreement.

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. The Company sold no shares of its common stock under the agreement during either of the three months ended March 31, 2023 or 2022. The Company terminated the agreement in March 2023.

April 2021 ATM Sales Agreement

In April 2021, the Company entered into a sales agreement with SVB Securities 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. The Company sold no shares of its common stock under the agreement during either of the three months ended March 31, 2023 or 2022. The Company terminated the agreement in March 2023.

Common Stock Warrants

In connection with an underwritten public offering in February 2018, the Company issued to the investors in that offering, warrants exercisable through February 2023 with an initial exercise price of $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 provided that, subject to certain limited exceptions, the exercise price of the warrants would be reduced each time the Company issued or sold (or was deemed to have issued or sold) securities for a net consideration per share less than the exercise price of those warrants in effect immediately prior to such issuance or sale. In addition, subject to certain exceptions, if the Company issued, sold or entered into any agreement to issue or sell securities at a price which varied or may vary with the market price of the shares of the Company's common stock, the warrant holders had the right to substitute such variable price for the exercise price of the warrant then in effect. In April 2019 and July 2020, in accordance with the price-based anti-dilution provision discussed above, the exercise price of these warrants was automatically reduced to $0.98 per share and to $0.96 per share, respectively. During the three months ended March 31, 2023, warrants to purchase 1,353,515 shares of common stock were exercised for gross proceeds of approximately $1.3 million and the remaining unexercised warrants expired on February 15, 2023. No warrants were exercised during the three months ended March 31, 2022.

As of March 31, 2023, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
6,500	$ 10.00	04/04/2026
6,500		

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 three months ended March 31, 2023 or March 31, 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 three months ended March 31, 2023. The exercise price of all options granted during the three months ended March 31, 2023 was equal to the market value of the Company's common stock on the date of grant. As of March 31, 2023, unamortized stock-based compensation expense of approximately $5.9 million will be amortized over a weighted average period of 2.71 years. At March 31, 2023, 7,078,916 shares of common stock were available for future awards granted under the 2022 Plan.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2022	6,612,554	$ 1.60
Granted	2,497,665	1.16
Exercised	—	
Cancelled/forfeited	—	
Expired	—	
Outstanding at March 31, 2023	9,110,219	$ 1.48
Exercisable at March 31, 2023	4,009,997	$ 1.51

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 March 31,	
	2023	2022
Research and development	$ 200,301	$ 174,613
General and administrative	$ 424,320	$ 357,796
Total	$ 624,621	$ 532,409

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 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 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 March 31, 2023, the Company reported operating lease right of use assets of approximately $368,000 in other non-current assets, approximately $336,000 in current portion of lease liabilities, and approximately $57,000 in lease liabilities long-term in the condensed consolidated balance sheets.

Total operating lease costs were approximately $139,000 and $169,000 for the three months ended March 31, 2023 and March 31, 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 $105,000 and $123,000 for the three months ended March 31, 2023 and March 31, 2022, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. At March 31, 2023, operating leases had a weighted average remaining lease term of 1.08 years.

As of March 31, 2023, future minimum lease payments under the Company's operating leases are as follows:

Remainder of 2023	$	317,000
2024		93,000
Total future minimum lease payments		410,000
Less: accreted interest		17,000
Total operating lease liabilities	$	393,000

7. COMMITMENTS AND CONTINGENCIES

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 March 31, 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 and DARE-204/214. 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 in the amount of $300,000 was for what is referred to as the "Phase I" segment of the project outlined in the Company's grant application, which is ongoing. Additional potential funding of up to approximately $2.0 million for the "Phase II" segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds. There is no guarantee the Company will receive any Phase II award.

The Company recorded credits to research and development expense for costs related to the NICHD award of $0 and approximately $17,000 during the three months ended March 31, 2023 and 2022, respectively. At March 31, 2023 and December 31, 2022, the Company did not record any receivable for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

DARE-LARC1

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

The Company recorded credits to research and development expense of approximately $32,000 and $165,000 for costs related to the NICHD award during the three months ended March 31, 2023 and 2022, respectively. The Company recorded a receivable of approximately $65,000 and $33,000 at March 31, 2023 and December 31, 2022, respectively, for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

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 $49,000 for costs related to the NICHD award during the three months ended March 31, 2023. The Company recorded a receivable of approximately $73,000 and $24,000 at March 31, 2023 and December 31, 2022, respectively, for expenses incurred through such date that it believes is eligible for reimbursement under the grant.

Other Non-Dilutive Grant Funding

2022 DARE-LBT Grant Agreement

In November 2022, the Company entered into an agreement with the Bill & Melinda Gates Foundation, or the Foundation, under which the Company was awarded $585,000 to support the development of DARE-LBT. The Company is required to apply the funds it receives under the agreement solely toward direct costs for the development of DARE-LBT1, 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. Any unspent funds are recorded as a deferred grant funding liability in the Company's condensed consolidated balance sheets.

The Company received the full amount of the award in November 2022. As of March 31, 2023, the Company has recorded a deferred grant funding liability of approximately $552,000 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 $49.0 million to support the development of DARE-LARC1. The Company is required to apply the funds it receives under the agreement solely toward direct costs for the development of DARE-LARC1, 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 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. The Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Any unspent funds are recorded as a deferred grant funding liability in the Company's condensed consolidated balance sheets.

The Company received an initial payment of approximately $11.5 million in 2021, and aggregate payments of approximately $12.4 million in 2022. As of March 31, 2023, the Company has received a cumulative total of approximately $23.9 million in non-dilutive funding under the agreement and recorded a deferred grant funding liability of approximately $15.3 million in the Company's condensed consolidated balance sheets. Additional payments are contingent upon the DARE-LARC1 program’s achievement of specified development and reporting milestones.

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 March 31,	
	2023	2022
Stock options	9,110,219	6,277,282
Warrants	6,500	1,381,015
Total	9,116,719	7,658,297

10. SUBSEQUENT EVENTS

ATM Sales

During April and May 2023, the Company sold an aggregate of 106,000 shares of common stock under its ATM equity offering program and received aggregate gross proceeds of approximately $109,000 and incurred sales agent commissions and fees of approximately $2,700 (see Note 4).

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.

Our first product, XACIATO [zah-she-AH-toe] (clindamycin phosphate) vaginal gel, 2%, was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in female patients 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. We anticipate the first commercial sale of XACIATO in the U.S. in the second quarter 2023.

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 are also exploring 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 three product candidates in advanced clinical development:

- **Ovaprene®**, a hormone-free, monthly intravaginal contraceptive;
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the female genitalia for the treatment of female sexual arousal disorder, or FSAD; and

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring, for the treatment of moderate to severe vasomotor symptoms, as part of menopausal hormone therapy;

Our portfolio also includes six product candidates in Phase 1 or Phase 1/2 clinical development or that we believe are Phase 1-ready:

- **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 vulvar vaginal atrophy;
- **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 containing bio-identical progesterone for luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth.

In addition, our portfolio includes four pre-clinical 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-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-LBT**, a novel hydrogel formulation for vaginal delivery of live biotherapeutics to support vaginal health; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

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. In 2023, we expect to focus our resources on advancement of Ovaprene, Sildenafil Cream, 3.6%, DARE-HRT1 and our other product candidates that have reached the human clinical study development phase. 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.

The process of developing and obtaining regulatory approvals for prescription drug and drug/device products in the United States and in foreign jurisdictions is inherently uncertain and requires the expenditure of substantial financial resources without any guarantee of success. As discussed below, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. To the extent we receive regulatory approvals, such as the FDA's approval of XACIATO, the commercialization of any product and compliance with subsequently applicable laws and regulations requires the expenditure of further substantial financial resources without any guarantee of commercial success. The amount of post-approval financial resources required for commercialization and the potential revenue we may receive from sales of any product will vary significantly depending on many factors, including whether, and the extent to which, we establish our own sales and marketing capabilities and/or enter into and maintain commercial collaborations with third parties with established commercialization infrastructure. 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 and service providers, 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, and exposure to cybersecurity threats and incidents.

The COVID-19 pandemic remains an evolving and uncertain risk to our business, operating results, financial condition and stock price. To date, we believe the pandemic contributed to a slower than expected initial pace of enrollment in our exploratory Phase 2b clinical study of Sildenafil Cream, 3.6% and delays in commencement of clinical studies and nonclinical testing for more than one of our earlier stage clinical programs, but it has not had a material adverse effect on our business as a whole. Future impacts may include delay or disruption of our clinical trials, including as a result of potential constraints or disruptions in the supply chains for our product candidates. Continued uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, healthcare systems, workplace environments and capital markets, preclude any prediction as to the ultimate effect of the pandemic on our business. See the risk factor in Part I, Item 1A of our 2022 10-K titled, *Business interruptions resulting from the COVID-19 pandemic or future public health crises, natural disasters or telecommunication and electrical failures may materially and adversely affect our business, operating results and financial condition.*

XACIATO

Activities in preparation for commercial launch of XACIATO (clindamycin phosphate) vaginal gel, 2% in the United States are ongoing and the first commercial sale is expected in the second quarter of 2023. Following the first commercial sale of XACIATO, we are entitled to receive a $2.5 million milestone payment from Organon and a $0.5 million payment from us to a third-party licensor will become payable. Under our exclusive global license agreement with Organon, we are also entitled to receive tiered double-digit royalties based on net sales and up to $180.0 million in tiered commercial sales milestones and regulatory milestones.

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 new drug application, or 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 following commercial launch, 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

In October 2022, we announced that the FDA approved an Investigational Device Exemption, or IDE, application allowing us to conduct a single arm, open-label pivotal contraceptive efficacy study of Ovaprene. 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 over an approximately 12-month (13 menstrual cycles) duration. 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 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. 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. Initiation of recruitment for the study is targeted for mid-2023.

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 fourth quarter of 2023 and 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 2022, we completed enrollment in our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% in premenopausal women with FSAD. During the multi-center, double-blind, placebo-controlled study, subjects use Sildenafil Cream, 3.6% and placebo cream in their home setting and document genital arousal symptoms and distress using patient reported outcome instruments. The primary efficacy endpoint of the study is a composite endpoint that includes patient-reported improvement in genital sensations of arousal and reduction in distress associated with FSAD. The exploratory study was designed to evaluate a number of different potential ways to ask women questions about their genital sensations and distress associated with FSAD (referred to as patient reported outcomes) in the at-home setting to help us assess the appropriate potential efficacy endpoints for future Phase 3 clinical studies. A total of approximately 160 to 170 subjects (approximately 80 to 85 subjects per arm) are expected to complete the study's 12 week double blind dosing period for inclusion in the topline data assessment, targeted for the second quarter 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, 3.6%, using thermography to assess the pharmacodynamic and pharmacokinetic characterization of Sildenafil Cream, 3.6%. We expect the Phase 1 thermography study will enroll approximately 15 women and be completed in 2023. Data from the study are expected to support the ongoing development of Sildenafil Cream, 3.6% as a potential treatment for FSAD.

DARE-HRT1

In October 2022 and January 2023, we announced topline results of our Phase 1/2 clinical study of DARE-HRT1 conducted by our wholly owned subsidiary in Australia. The randomized, open-label, two arm, parallel group study evaluated the pharmacokinetics (PK) of two versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study also collected safety, usability, acceptability and symptom-relief data including the vasomotor symptoms, or VMS, as well as the vaginal symptoms of menopause. Based on pre-IND communications with the FDA and the topline PK, data from the Phase 1/2 study, 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 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. Ongoing activities to support progressing DARE-HRT1 directly into a Phase 3 clinical study to support registration include manufacturing and non-clinical studies to support an investigational new drug, or IND, submission to the FDA and the IND-opening Phase 3 study.

DARE-VVA1

In November 2022, we announced topline results from of our Phase 1/2 clinical study of DARE-VVA1 conducted by our wholly owned subsidiary in Australia. The randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study enrolled 17 postmenopausal women with VVA and evaluated the safety, tolerability, plasma PK and pharmacodynamics (PD) of DARE-VVA1. We believe the results of the Phase 1/2 study support ongoing development of DARE-VVA1 as a potential hormone-free treatment for moderate to severe vulvar vaginal atrophy. We are conducting activities to support an IND submission to the FDA and an IND-opening Phase 2 clinical study.

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 are conducting development activities in preparation for Phase 1 clinical studies of DARE-204 and DARE-214 by our wholly-owned subsidiary in Australia. We do not expect to commence the Phase 1 studies in 2023.

DARE-FRT1 and DARE-PTB1

We are conducting development activities in preparation for Phase 1 clinical studies of DARE-FRT1 and DARE-PTB1. We do not expect to commence clinical development activities of these product candidates in 2023.

Recent Events

New ATM Sales Agreement

On March 31, 2023, we entered into a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, and Cantor Fitzgerald & Co., or Cantor, to sell shares of our common stock from time to time through an "at-the-market," or ATM, equity offering program under which Stifel and Cantor act as our agent. We 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 we and Stifel and Cantor agree, plus certain legal expenses. Shares of our common stock sold under the agreement will be issued pursuant to our 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 our common stock under the sales agreement, and any subsequent prospectus supplement related to the offering of shares of our common stock under the sales agreement.

Termination of 2021 ATM Sales Agreements

In April and October 2021, we entered into common stock sales agreements with SVB Securities LLC relating to the offering and sale of shares of our common stock from time to time in ATM offerings through SVB Securities, acting as sales agent. In March 2023, we provided notice to SVB Securities to terminate both agreements, and the agreements terminated on March 30, 2023.

Financial Overview

Revenue

To date we have generated $10.0 million in revenue, all of which represents the upfront payment under our license agreement with Organon to commercialize XACIATO, which is recognized as license fee revenue. 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, research and development payments in connection with strategic collaborations. In the future and for an interim period, 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 the commercialization of XACIATO is not 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

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.

We recognize the Australian Research and Development Tax Incentive Program, or the Tax Incentive, as a reduction of research and development expense. 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 months ended March 31, 2023 and 2022, we recognized contra-research and development expense of approximately $2.6 million and $1.1 million, respectively.

In 2022, our research and development expenses consisted primarily of costs associated with the continued development of Ovaprene and Sildenafil Cream 3.6%. We expect research and development expenses to increase in 2023 and beyond as we continue to invest in the development of and seek regulatory approval for our clinical-stage and Phase 1-ready product candidates and as any other potential product candidates we may develop are advanced into and through clinical trials in the pursuit of regulatory approvals. Such activities will require a significant increase in investment in regulatory support, clinical supplies, inventory build-up related costs, and the payment of success-based milestones to licensors. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to, among other factors, license fee and/or milestone payments.

Conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may not obtain regulatory approval for any product candidate on a timely or cost-effective basis, or at all. The probability of success of our product candidates may be affected by numerous factors, including clinical results and data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we cannot accurately determine the duration and completion costs of development projects or when and to what extent we will generate revenue from the commercialization of any of our product candidates.

License 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. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related 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 March 31, 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 March 31,		Change	
	2023	2022	$	%
Operating expenses:				
General and administrative	3,337,426	2,569,987	767,439	30 %
Research and development	5,020,223	5,805,462	(785,239)	(14)%
License fee expenses	25,000	25,000	—	— %
Total operating expenses	8,382,649	8,400,449	(17,800)	— %
Loss from operations	(8,382,649)	(8,400,449)	17,800	— %
Other income	340,148	1,779	338,369	19020 %
Net loss	$ (8,042,501)	$ (8,398,670)	$ 356,169	(4)%
Other comprehensive loss:				
Foreign currency translation adjustments	(22,005)	(9,150)	(12,855)	140 %
Comprehensive loss	$ (8,064,506)	$ (8,407,820)	$ 343,314	(4)%

General and administrative expenses

The increase of approximately $0.8 million in general and administrative expenses for the three months ended March 31, 2023 as compared to the three months ended March 31, 2022 was primarily attributable to increases in (i) commercial-readiness expenses of approximately $0.2 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) general corporate overhead, including rent and facilities expenses, of approximately $0.1 million, (iv) professional services expense of approximately $72,000, (v) stock-based compensation expense of approximately $67,000, (vi) and personnel costs of approximately $49,000.

Research and development expenses

The decrease of approximately $0.8 million in research and development expenses for the three months ended March 31, 2023 as compared to the three months ended March 31, 2022 was primarily attributable to decreases in expenses related to clinical trial and manufacturing and regulatory affairs activities for our clinical-stage product candidate Ovaprene of approximately $1.1 million and decreases in costs related to our ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical study of approximately $0.3 million, partially offset by increases in costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $0.6 million.

License fee expenses

For each of the three months ended March 31, 2023 and March 31, 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 increase of $0.3 million in other income for the three months ended March 31, 2023 as compared to the three months ended March 31, 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 March 31, 2023, our accumulated deficit was approximately $149.1 million, our cash and cash equivalents were approximately $19.8 million, our deferred grant funding liabilities under our grant agreements related to DARE-LARC1 and DARE-LBT were approximately $15.3 million and $0.6 million, respectively, and our working capital was approximately $5.2 million. The aggregate $15.8 million of deferred grant funding liabilities is included in our cash and cash equivalents, and represents grant funds received 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 our entire operations. We incurred a loss from operations of approximately $8.0 million and had negative cash flow from operations of approximately $16.1 million during the three months ended March 31, 2023.

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 existing product candidates and as we seek to potentially acquire, license and develop additional 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.

Based on current development plans for our product candidates, we anticipate both our general and administrative and research and development expenses to increase in 2023 compared to 2022 as we continue to focus on the advancement of Ovaprene, Sildenafil Cream, 3.6%, DARE-HRT1 and our other product candidates that have reached the human clinical study development phase. If the first commercial sale of XACIATO in the U.S. occurs in the second quarter of 2023 as expected, we will receive a $2.5 million milestone payment and we will be eligible to receive royalty payments at rates in the low double-digits based on annual net sales of XACIATO. After taking into account our royalty payment obligations under our in-license agreement for XACIATO, we do not expect royalty payments received during 2023 to materially impact our cash resources or requirements. Our general and administrative expenses for 2023 are expected to increase primarily due to increased personnel costs and other general corporate overhead, and are expected to include costs related to commercial-readiness activities and obtaining commercial supply of XACIATO from our contract manufacturer. Under the terms of our license agreement with Organon, Organon will purchase XACIATO from us at a price equal to our manufacturing costs plus a single digit percentage markup. As a result, we do not anticipate our costs for providing XACIATO to Organon will have a material impact on our cash resources and requirements. Following commercial launch of XACIATO, we expect our general and administrative expenses will include payments by us under our in-license agreement for XACIATO, including a $500,000 milestone payment upon first commercial sale of XACIATO in the U.S. and royalty payments at rates in the high single-digit to low double-digits based on annual net sales of XACIATO. The amount of our research and development expenses for 2023 is difficult to predict with certainty and will depend on the pace and extent of our research and development activities. Factors that impact the pace and extent of our research and development activities and, therefore our research and development spend include, without limitation, our cash resources, reprioritization of development programs and activities, the scope, timing of commencement, and rate of progress of our clinical trials and preclinical studies, the cost and timing of manufacture and receipt of clinical supplies, timing of regulatory approval of a clinical study or alignment on study design, the results of our clinical trials and preclinical studies, and the extent to which we establish strategic collaborations or other arrangements and the terms of such arrangements.

Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. The amount and timing of our capital needs have and will continue to depend highly on many factors, including the pace at which our clinical development programs proceed and the expenses associated therewith. 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. We can control the timing of when we incur a majority of those expenses. Our research and development expenses for the remainder of 2023 will be primarily associated with the anticipated completion of our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6%, manufacturing activities in connection with our pivotal Phase 3 clinical study of Ovaprene, and variable expenses for our other programs, the timing of when we incur such expenses we can control. We closely monitor our cash resources and, if all of our clinical development programs proceed on currently anticipated timelines, we will need additional capital by the middle of this year to fund operations and the continued development of all such programs on such timelines. We are in ongoing discussions with multiple potential third-party sources of additional capital and we believe that we will be able to obtain sufficient capital when needed in a manner that will not materially impact the development of our product candidates. However, 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 as and when needed.

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 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, failure of the U.S. government to raise the federal debt ceiling, impacts of the war in Ukraine, 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. 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 Part I, Item 1A of our 2022 10-K 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.*

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. 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.

Cash Flows

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

	Three months ended March 31,	
	2023	2022
Net cash used in operating activities	$ (16,117,571)	$ (12,343,473)
Net cash used in investing activities	—	(4,553)
Net cash provided by financing activities	1,299,375	—
Effect of exchange rate changes on cash and cash equivalents	(22,005)	(9,150)
Net decrease in cash and cash equivalents	$ (14,840,201)	$ (12,357,176)

Net cash used in operating activities

Cash used in operating activities for the three months ended March 31, 2023 included the net loss of $8.0 million, decreased by non-cash stock-based compensation expense of approximately $0.6 million. A component providing operating cash was an increase in accounts payable of approximately $0.7 million. Components reducing operating cash were a decrease in accrued expenses of approximately $5.4 million, a decrease in deferred grant funding of approximately $2.5 million, an increase in prepaid expenses of approximately $0.4 million, an increase in other receivables of approximately $0.7 million, and a one-time cybersecurity fraud loss of $0.2 million, net of insurance reimbursement, which was recognized in general and administrative expenses.

Cash used in operating activities for the three months ended March 31, 2022 included the net loss of $8.4 million, decreased by non-cash stock-based compensation expense of approximately $0.5 million. Components providing operating cash were an increase in accrued expenses of approximately $0.4 million and an increase in accounts payable of approximately $0.7 million**.** Components reducing operating cash were an increase in prepaid expenses of approximately $4.3 million, a decrease in deferred grant funding of approximately $0.8 million, and an increase in other receivables of approximately $0.6 million.

Net cash used in investing activities

No cash was used in investing activities for the three months ended March 31, 2023. Net cash used in investing activities for the three months ended March 31, 2022 was approximately $4,600.

Net cash provided by financing activities

Cash provided by financing activities for the three months ended March 31, 2023 consisted of approximately $1.3 million from sales of our common stock upon the exercise of warrants. No cash was provided by financing activities for the three months ended March 31, 2022.

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, 3.6%, and under other agreements related to our other clinical and preclinical candidates. During 2023, based on our current expectations regarding the development of our product candidates and sales of XACIATO, we expect to pay approximately $4.1 million in royalty and milestone payments under the license and development agreements. For further discussion of these potential payments, see Note 3 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 March 31, 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. There have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in our 2022 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(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.

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
3.1	Third Amended and Restated By-laws	8-K	001-36395	1/27/23	3.1	
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

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: May 11, 2023

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

Date: May 11, 2023

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

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: May 11, 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: May 11, 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 March 31, 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: May 11, 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 March 31, 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: May 11, 2023

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