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 June 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36395

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

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

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

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

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

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

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

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

Large Accelerated Filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	o		

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

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

As of August 9, 2023, 87,785,166 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.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	June 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 13,329,101	$ 34,669,605
Other receivables	572,466	1,703,160
Prepaid expenses	8,069,622	6,665,988
Other current assets	272,100	—
Total current assets	22,243,289	43,038,753
Property and equipment, net	45,785	64,908
Other non-current assets	920,880	722,722
Total assets	$ 23,209,954	$ 43,826,383
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 6,541,115	$ 2,027,953
Accrued expenses	4,193,799	10,894,016
Deferred grant funding	13,694,085	18,303,567
Current portion of lease liabilities	271,825	398,391
Total current liabilities	24,700,824	31,623,927
Deferred revenue	1,205,206	1,000,000
Lease liabilities long-term	23,326	90,346
Total liabilities	25,929,356	32,714,273
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value, 5,000,000 shares authorized; None issued and outstanding	—	—
Common stock, $0.0001 par value; 240,000,000 shares authorized; 86,633,588 and 84,825,481 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	8,663	8,482
Accumulated other comprehensive loss	(404,467)	(351,311)
Additional paid-in capital	155,555,775	152,529,579
Accumulated deficit	(157,879,373)	(141,074,640)
Total stockholders' equity (deficit)	(2,719,402)	11,112,110
Total liabilities and stockholders' equity (deficit)	$ 23,209,954	$ 43,826,383

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue				
License fee revenue	$ —	$ 10,000,000	$ —	$ 10,000,000
Total revenue	—	10,000,000	—	10,000,000
Operating expenses				
General and administrative	2,920,672	2,792,894	6,258,098	5,362,881
Research and development	6,043,684	6,797,784	11,063,907	12,603,247
License fee expense	25,000	25,000	50,000	50,000
Total operating expenses	8,989,356	9,615,678	17,372,005	18,016,128
Income (loss) from operations	(8,989,356)	384,322	(17,372,005)	(8,016,128)
Other income	227,124	29,676	567,272	31,456
Net income (loss)	$ (8,762,232)	$ 413,998	$ (16,804,733)	$ (7,984,672)
Foreign currency translation adjustments	(31,151)	(135,869)	(53,156)	(145,019)
Comprehensive income (loss)	$ (8,793,383)	$ 278,129	$ (16,857,889)	$ (8,129,691)
Income (loss) per common share:				
Basic	$ (0.10)	$ —	$ (0.19)	$ (0.10)
Diluted	$ (0.10)	$ —	$ (0.19)	$ (0.10)
Weighted average number of shares outstanding:				
Basic	86,403,117	84,682,765	86,976,129	84,682,765
Diluted	86,403,117	85,369,424	86,976,129	84,682,765

See accompanying notes.

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

Six Months Ended June 30, 2023

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

Six Months Ended June 30, 2022

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

See accompanying notes.

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

	Six months ended June 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (16,804,733)	$ (7,984,672)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	19,123	10,546
Stock-based compensation expense	1,274,807	1,069,930
Non-cash operating lease cost	(11,811)	9,940
Changes in operating assets and liabilities:		
Accounts receivable	—	(10,000,000)
Other receivables	1,130,694	(992,334)
Prepaid expenses	(1,403,634)	(3,427,756)
Other current assets	(272,100)	—
Other non-current assets	(44,934)	91,690
Accounts payable	4,513,162	(988,855)
Accrued expenses	(6,700,216)	3,211,123
Deferred grant funding	(4,609,482)	(1,791,598)
Deferred revenue	205,206	—
Net cash used in operating activities	(22,703,918)	(20,791,986)
Cash flows from investing activities		
Purchases of property and equipment	—	(5,369)
Net cash used in investing activities	—	(5,369)
Cash flows from financing activities		
Net proceeds from issuance of common stock	452,195	1,218,750
Proceeds from the exercise of common stock warrants	1,299,375	120,149
Net cash provided by financing activities	1,751,570	1,338,899
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(53,156)	(145,019)
Net change in cash, cash equivalents and restricted cash	(21,005,504)	(19,603,475)
Cash, cash equivalents and restricted cash, beginning of period	34,669,605	51,674,087
Cash, cash equivalents and restricted cash, end of period	$ 13,664,101	$ 32,070,612
Reconciliation of cash, cash equivalents and restricted cash to amounts reported in the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 13,329,101	$ 32,070,612
Restricted cash included in other non-current assets	335,000	—
Total cash, cash equivalents and restricted cash	$ 13,664,101	$ 32,070,612
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, Cash Equivalents and Restricted Cash

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

Going Concern

The Company prepared its condensed consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company has a history of losses from operations, expects negative cash flows from its operations to continue for the foreseeable future, and expects that its net losses will continue for at least the next several years as it develops and seeks to bring to market its existing product candidates and to potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

As of June 30, 2023, the Company had an accumulated deficit of approximately $157.9 million, cash and cash equivalents of approximately $13.3 million, deferred grant funding liabilities under the Company's grant agreements related to DARE-LARC1 and DARE-LBT of approximately $13.7 million, and a working capital deficit of approximately $2.5 million. Substantially all of the Company's cash and cash equivalents at June 30, 2023 represented grant funds received under such grant agreements that may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support the entire operations of the Company. For the six months ended June 30, 2023, the Company incurred a net loss of approximately $16.8 million and had negative cash flow from operations of approximately $22.7 million.

Based on the Company's current operating plan estimates, the Company does not have sufficient cash to satisfy its working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. The Company will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current strategy.

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

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

Fair Value of Financial Instruments

GAAP defines fair value as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date, and also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available. The three-level hierarchy of valuation techniques established to measure fair value is defined as follows:

- Level 1: inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of assets or liabilities.
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables present the classification within the fair value hierarchy of financial assets and liabilities that are remeasured on a recurring basis as of June 30, 2023 and December 31, 2022. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) or using unobservable inputs (Level 3) as of June 30, 2023 or December 31, 2022.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at June 30, 2023				
Current assets:				
Cash equivalents [1]	$ 10,837,944	$ —	$ —	$ 10,837,944
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 June 30, 2023, the Company has not recognized any collaboration revenues.

License Fee Revenue. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. To date, the Company has recognized $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 June 30, 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 June 30, 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 June 30, 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 June 30, 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 June 30, 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 a $10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue.

Under the terms of the license agreement in effect as of June 30, 2023, 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. Subsequent to June 30, 2023, the Company and Organon entered into an amendment to the license agreement, which changed some of the payment terms. (See Note 10, Subsequent Events.)

At the inception of the agreement, the Company concluded that the transaction price was $10.0 million and should not include the variable consideration related to unachieved development, regulatory, commercial milestones and future sales-based royalty payments. This consideration was determined to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue. The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. For the quarter ended June 30, 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 June 30, 2023, neither of the foregoing had occurred. The $1.0 million payment is recorded as long-term deferred license revenue in the Company's consolidated balance sheets at June 30, 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. 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 June 30, 2023, no payments have been made under this agreement.

MBI Acquisition

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

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

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

TriLogic and MilanaPharm License Agreement / Hammock Assignment Agreement

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

Under the terms of the License Agreement, the Company paid clinical and regulatory development milestones in the aggregate of $300,000 to MilanaPharm, the final payment of $250,000 was expensed in 2021. The Company may also pay MilanaPharm up to $500,000 upon the first commercial sale in the United States of the first licensed product for each vaginal and urological use, and up to $250,000 upon the first commercial sale in the United States of each successive licensed products for each vaginal or urological use. In 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 June 30, 2023.

Pear Tree Acquisition

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

Under the terms of the merger agreement, the Company agreed to pay the former stockholders of Pear Tree: (a) up to $15.5 million in the aggregate upon 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., or Catalent, under which Catalent granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, to make, have made, use, have used, sell, have sold, import and have imported products and processes, and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Catalent to make, have made, use, have used, sell, have sold, import and have imported products and processes. The Company is entitled to sublicense the rights granted to it under this agreement.

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

Adare Development and Option Agreement

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

SST License and Collaboration Agreement

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

SST will be eligible to receive payments of up to $18.0 million in the aggregate upon 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 six months ended June 30, 2023, the Company sold 454,592 shares of common stock under this agreement and received aggregate gross proceeds of approximately $463,000 and incurred sales agent commissions and fees of approximately $11,000.

October 2021 ATM Sales Agreement

In October 2021, the Company entered into a sales agreement with SVB Securities LLC (formerly known as SVB Leerink LLC) to sell shares of its common stock from time to time through an ATM equity offering program under which SVB Securities acted as the Company's agent. The Company sold no shares of its common stock under the agreement during either of the six months ended June 30, 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 six months ended June 30, 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 six months ended June 30, 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 six months ended June 30, 2022.

As of June 30, 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 six months ended June 30, 2023 or June 30, 2022.

Amended and Restated 2014 Stock Incentive Plan

The Amended and Restated 2014 Stock Incentive Plan, or the Amended 2014 Plan, provided for the grant of options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, officers and directors, and consultants and advisors. There were 2,046,885 shares of common stock authorized for issuance under the Amended 2014 Plan when it was approved by the Company's stockholders in July 2018. The number of authorized shares increased annually on the first day of each fiscal year by the least of (i) 2,000,000, (ii) 4% of the number of outstanding shares of common stock on such date, or (iii) an amount determined by the Company's board of directors. On January 1, 2022, the number of authorized shares increased by 2,000,000 to 2,201,855. As a result of the approval of the 2022 Plan (as defined below) by the Company's stockholders on June 23, 2022, no further awards have been or will be granted under the Amended 2014 Plan. Outstanding awards previously granted under the Amended 2014 Plan continue to remain outstanding in accordance with their terms.

2022 Stock Incentive Plan

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

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

Summary of Stock Option Activity

The table below summarizes stock option activity under the Company's stock incentive plans and related information for the six months ended June 30, 2023. The exercise price of all options granted during the six months ended June 30, 2023 was equal to the market value of the Company's common stock on the date of grant. As of June 30, 2023, unamortized stock-based compensation expense of approximately $5.6 million will be amortized over a weighted average period of 2.47 years. The number of shares of common stock available for future awards granted under the 2022 Plan at June 30, 2023 was 6,718,916.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2022	6,612,554	$ 1.60
Granted	2,857,665	1.13
Exercised	—	
Cancelled/forfeited	—	
Expired	—	
Outstanding at June 30, 2023	9,470,219	$ 1.46
Exercisable at June 30, 2023	4,769,873	$ 1.50

Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 210,198	$ 171,938	$ 410,499	$ 346,552
General and administrative	439,988	365,583	864,308	723,378
Total	$ 650,186	$ 537,521	$ 1,274,807	$ 1,069,930

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 entered into a new lease for general office space in June 2023 that will commence on December 1, 2023 and will create an obligation to pay approximately $1.4 million over the lease period of three years.

MBI previously leased warehouse space in Billerica, Massachusetts, under a lease that commenced on October 1, 2016 and terminated on March 31, 2022.

Under the terms of each lease, the lessee pays base annual rent (subject to an annual fixed percentage increase), plus property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The leases do not require material variable lease payments, residual value guarantees or restrictive covenants.

The leases do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company uses an incremental borrowing rate consisting of the current prime rate plus 200 basis points for operating leases that commenced prior to January 2019 (and all of the Company's operating leases commenced prior to such date). The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At June 30, 2023, the Company reported operating lease ROU assets of approximately $276,000 in other non-current assets, approximately $272,000 in current portion of lease liabilities, and approximately $23,000 in lease liabilities long-term in the condensed consolidated balance sheets.

Total operating lease costs were approximately $145,000 and $284,000 for the three and six months ended June 30, 2023, respectively, and $150,000 and $340,000 for the three and six months ended June 30, 2022, respectively. Operating lease costs consist of monthly lease payments expense, common area maintenance and other repair and maintenance costs and are included in general and administrative expenses in the condensed consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $105,000 and $209,000 for the three and six months ended June 30, 2023, respectively, and $80,000 and $203,000 for the three and six months ended June 30, 2022, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. At June 30, 2023, operating leases had a weighted average remaining lease term of 0.83 years.

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

Remainder of 2023	$	213,000
2024		93,000
Total future minimum lease payments		306,000
Less: accreted interest		10,000
Total operating lease liabilities	$	296,000

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 June 30, 2023 was $0.5 million.

8. GRANT AWARDS

NICHD Non-Dilutive Grant Funding

The Company has received notices of awards and non-dilutive grant funding from NICHD to support the development of DARE-PTB1, DARE-LARC1 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 $721 during the three and six months ended June 30, 2023, and $2,500 and $19,500 during the three and six months ended June 30, 2022, respectively. At June 30, 2023 the Company recorded a receivable for expenses incurred through such date that it believes are reimbursable under the grant of $721. No receivable was recorded at December 31, 2022.

DARE-LARC1

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

The Company recorded credits to research and development expense of approximately $0 and $32,000 for costs related to the NICHD award during the three and six months ended June 30, 2023, respectively, and $27,800 and $193,000 for the three and six months ended June 30, 2022, respectively. The Company recorded a receivable of approximately $33,000 at December 31, 2022 for expenses incurred through such date that were subsequently reimbursed under the grant. No receivable was recorded at June 30, 2023. The Company received aggregate reimbursements under the NICHD award of approximately $278,000 during the grant period, which ended in June 2023. No further funds are available under this award.

DARE-204 and DARE-214

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

The Company recorded credits to research and development expense of approximately $32,700 and $81,500 for costs related to the NICHD award during the three and six months ended June 30, 2023, respectively, with no such credits recorded in the same periods of the prior year. The Company recorded a receivable of approximately $33,040 and $24,000 at June 30, 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-LBT, 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 and any funds spent that have not yet been depreciated or expensed 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 June 30, 2023, the Company has recorded a deferred grant funding liability of approximately $544,000 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 and any funds spent that have not yet been depreciated or expensed 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 June 30, 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 $13.1 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Stock options	9,470,219	6,053,156	9,470,219	6,417,533
Warrants	6,500	1,058,733	6,500	1,381,015
Total	9,476,719	7,111,889	9,476,719	7,798,548

10. SUBSEQUENT EVENTS

ATM Sales

During July and August 2023, the Company sold an aggregate of 1,151,578 shares of common stock under its ATM equity offering program and received aggregate gross proceeds of approximately $946,000 and incurred sales agent commissions and fees of approximately $22,000 (See Note 4, Stockholders' Equity).

NICHD Non-Dilutive Grant Award

On July 28, 2023, the Company received a notice of award of a grant from NICHD of approximately $385,000 to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds will support activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida, or USF, which are to occur over a 12-month period. The Company will track expenses eligible for reimbursement under the grant award and submit a detailed accounting of such expenses to receive payment of the grant funds. The amounts of any such payments will be recognized in the Company's statement of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the project period.

Insurance Financing

On July 18, 2023, the Company obtained financing for certain director and officer and other liability insurance premiums. The agreement for such financing assigns to the lender a first priority lien on and a security interest in the financed insurance policies and any additional premium required in the financed insurance policies including (a) all returned or unearned premiums, (b) all additional cash contributions or collateral amounts assessed by the insurance companies in relation to the financed insurance policies and financed by the lender, (c) any credits generated by the financed insurance policies, (d) dividend payments, and (e) loss payments which reduce unearned premiums. If any circumstances exist in which premiums related to any financed insurance policy could become fully earned in the event of loss, the lender will be named a loss-payee with respect to such policy.

The total premiums, taxes and fees financed is approximately $0.8 million with an annual interest rate of approximately 8.0%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promises to pay the lender the amount financed plus interest and other charges permitted under the agreement. The Company will pay the insurance financing through monthly installment payments through April 20, 2024. The amount financed will be recognized as an insurance financing payable in the Company's consolidated balance sheets.

Amendment to Exclusive License Agreement with Organon

On July 4, 2023, the Company entered into an amendment to its exclusive license agreement with Organon to commercialize XACIATO. Under the amendment, Organon agreed to pay $1.0 million to the Company as reimbursement for fees paid to the FDA in connection with the submission of the new drug application for XACIATO (known as PDUFA fees) and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, which will be recognized as license fee revenue in the third quarter of 2023. The Company received such amount in July 2023. The amount payable by Organon to the Company following the first commercial sale of a licensed product in the United States was revised to $1.8 million.

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 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 also explore opportunities to expand our portfolio by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on women's health.

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

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

- **DARE-HRT1**, an intravaginal ring designed to deliver both bio-identical estradiol and progesterone together, continuously over a 28-day period, for the treatment of moderate-to-severe vasomotor symptoms, as part of menopausal hormone therapy; and
- **DARE-VVA1**, a proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate to severe vulvovaginal atrophy.

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

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

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

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

Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or regulatory approval. We expect our research and development expenses will continue to represent the majority of our operating expenses for at least the next twelve months. For the remainder of 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, service providers and suppliers, being able to develop commercially viable products in a timely and cost-effective manner, dependence on intellectual property we own or in-license and the need to protect that intellectual property and maintain those license agreements, uncertainty of market acceptance of products, uncertainty of third-party payor coverage, pricing and reimbursement for products, rapid technology change, intense competition, compliance with government regulations, product liability claims, and exposure to cybersecurity threats and incidents.

XACIATO

Activities in preparation for commercial launch of XACIATO (clindamycin phosphate) vaginal gel, 2% in the United States, including manufacturing-related activities, are ongoing and the first commercial sale is expected in 2023. In July 2023, we entered into an amendment to our exclusive global license agreement with Organon and received $1.0 million from Organon as reimbursement for fees paid to the FDA in connection with submission of the new drug application (NDA) for XACIATO (known as PDUFA fees) and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, which will be recognized as license fee revenue in the third quarter of 2023. Following the first commercial sale of XACIATO, we are entitled to receive a $1.8 million milestone payment from Organon and a $0.5 million payment from us to a third-party licensor will become payable. Under our 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 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. We will target having approximately 250 women complete approximately 12-months (13 menstrual cycles) of use of Ovaprene. Based on typical dropout rates for contraceptive efficacy studies, we will seek to enroll more than double the number of subjects we target to complete 13 menstrual cycles of use. We have been working with our collaborators at the National Institutes of Health, or NIH, and at Bayer to review and implement study design considerations provided by the FDA with its IDE approval letter, which we believe will further position the Phase 3 study to collect safety and effectiveness data to enable the preparation of, and to support the submission of, a premarket approval, or PMA, application for Ovaprene. The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. If successful, we expect the study to support a PMA application to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene. Subject enrollment in the study is targeted to begin in the fourth quarter of 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. In the future, depending on the duration of the enrollment period and number of subjects enrolled in the Phase 3 study, there may be costs associated with the study that are not reflected in the current budget under the CRADA, in which case, we and NICHD would discuss the mechanism to potentially provide for additional future payments by us in support of the Phase 3 study. We do not expect any such potential additional amounts to be payable in 2023.

Sildenafil Cream, 3.6%

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

A total of 252 subjects were enrolled in the 4-week single-blind placebo run-in period and a total of 200 subjects were randomized to the 12-week double-blind dosing period. A total of seven subjects were randomized but not treated in the double-blind dosing period. In the intent to treat (ITT) population, 99 subjects were randomized to the Sildenafil Cream group and 94 subjects were randomized to the placebo cream group. A co-primary endpoint of the study evaluated the efficacy of Sildenafil Cream compared to placebo as measured by change from baseline to end of study (the assessment 12 weeks after randomization) in the Arousal-Sensation Domain of the 28-item Sexual Function Questionnaire. The endpoint did not achieve statistical significance. However, the change at end of study in the Sildenafil Cream group was consistent with how women reported meaningful improvement in an exit interview at the end of the study. The other co-primary endpoint evaluated the efficacy of Sildenafil Cream compared to placebo as measured by change from baseline to end of study in the score for feeling concerned by difficulties with sexual arousal. The change was assessed using one question from the previously validated Female Sexual Distress Scale – Desire, Arousal and Orgasm Survey. This assessment did not differentiate Sildenafil Cream from placebo. The secondary endpoint evaluated the efficacy of Sildenafil Cream compared to placebo as measured by change from baseline to end of study in the number of satisfactory sexual events based on the subjects' response to a question answered and recorded via electronic diary within 24 hours after each sexual event. When measured at the 4- and 8-week mark after randomization, subjects in the Sildenafil Cream group had a higher proportion of satisfying sexual events during the prior four weeks (68.6% and 74.1% at the 4- and 8-week mark, respectively) compared to subjects in the placebo group (47.9% and 67.9% at the 4- and 8-week mark, respectively) (week 4 P value = 0.04).

Subjects in the Sildenafil Cream group showed improvements in multiple pre-specified exploratory endpoints that evaluated various aspects of the sexual experience, including concerns about difficulties with sexual arousal, arousal lubrication, achievement and pleasure of orgasm, and sexual desire. In an exploratory endpoint regarding concerns about difficulties with sexual arousal, when asked about their overall impression of change regarding their concerns about difficulties with sexual arousal, women treated with Sildenafil Cream were more likely to report an overall improvement. Based on responses to the question at the 4-, 8- and 12-week mark after randomization, 44% to 49% of the subjects treated with Sildenafil Cream reported an overall improvement compared to 37% to 44% of the subjects treated with placebo (P value < 0.01). Exploratory endpoints related to arousal lubrication, orgasm, and sexual desire demonstrated important differences between subjects in the Sildenafil Cream group compared to the placebo group as measured by change from baseline to the 8-week mark after randomization, at P value = 0.059, P value = 0.066, and P value = 0.022, respectively. Improvements in arousal lubrication, orgasm, and sexual desire in the Sildenafil Cream group achieved maximum separation from placebo at the 8-week mark after randomization and these improvements were maintained through end of study, demonstrating persistence while on treatment. In the placebo group, no such trends were observed, with no such improvements achieved at the 8-week mark. While improvements achieved in the Sildenafil Cream group in arousal lubrication, orgasm, and sexual desire by the 8-week mark persisted through end of study, no endpoint achieved statistical significance at end of study. Sildenafil Cream was generally safe and well-tolerated in the study for both the female subjects and their male partners enrolled in the study. There were no treatment related serious adverse events and the majority of treatment related adverse events were mild in severity.

We believe data from the Phase 2b RESPOND study support Sildenafil Cream's potential to improve female genital arousal and orgasm, as well as sexual desire, suggesting that FSAD and/or FSIAD are potential indications to pursue, and we plan to advance clinical development of Sildenafil Cream into a Phase 3 pivotal study. Phase 3 clinical study design, including primary and secondary efficacy endpoints, study duration, timing for efficacy endpoint assessment, use of endpoints that reduce burden on study subjects (e.g., 28-day recall assessments as opposed to recall assessments within 24 hours after each sexual event), and inclusion/exclusion criteria for study subjects, will be determined following psychometric analyses we are conducting of the Phase 2b RESPOND study data and future discussions with the FDA, including an end of Phase 2 meeting with the FDA.

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

DARE-HRT1

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 PK of two versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg intravaginal ring (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 vulvovaginal atrophy (VVA), and evaluated the safety, tolerability, plasma PK and 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 VVA. 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

Positive Topline Data from Exploratory Phase 2b RESPOND Study of Sildenafil Cream

As discussed above, in June 2023, we announced topline data from our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, and in July 2023, we announced additional data from the study. See "Clinical-Stage Program Updates-Sildenafil Cream, 3.6%," above.

Amendment to Exclusive License Agreement with Organon

As discussed above, in July 2023, we entered into an amendment to our exclusive license agreement with Organon to commercialize XACIATO. See "XACIATO," above.

Receipt of Cash Rebate under Australian Research and Development Tax Incentive Program

In June 2023, we received a cash rebate from the government of Australia in the amount of approximately $1.6 million for research and development expenditures incurred in Australia in 2022. The rebate is accounted for as a reduction to research and development expenses.

NICHD Non-Dilutive Grant Award

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

Financial Overview

Revenue

To date we have generated $11.0 million in revenue, $10.0 million of which represents the upfront payment under our license agreement with Organon to commercialize XACIATO, which is recognized as license fee revenue, and $1.0 million of which represents the reimbursement for PDUFA fees and other manufacturing expenses and to support continued advancement of the development and commercialization of XACIATO, which will be recognized as license fee revenue in the third quarter of 2023. In the future, we may generate revenue from royalties and commercial milestones based on the net sales of XACIATO, from product sales of other approved products, if any, and from license fees, milestone payments, and research and development payments in connection with strategic collaborations. In the future and for an interim period, 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

The majority of our operating expenses during a fiscal year are research and development expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. Research and development expenses include research and development costs for our product candidates and transaction costs related to our acquisitions. We recognize all research and development expenses as they are incurred. Research and development expenses consist primarily of:

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

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

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

We receive funding through grants that support activities related to the development of certain of our product candidates. As we incur eligible expenses under those grants, we recognize grant funding in the statements of operations as a reduction to research and development expense (contra-research and development expense). For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies – Grant Funding, to our consolidated financial statements contained in our 2022 10-K and Note 8, Grant Awards, to our condensed consolidated financial statements contained in this report. For the three and six months ended June 30, 2023 and 2022, we recognized contra-research and development expenses of approximately $2.2 million and $4.7 million, respectively, and $1.0 million and $2.0 million, respectively.

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

License Fee Expenses

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

General and Administrative Expenses

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services. 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 June 30, 2023 and 2022 (Unaudited)

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

	Three Months Ended June 30,		Change	
	2023	2022	$	%
Revenues:				
License fee revenue	$ —	$ 10,000,000	$ (10,000,000)	(100)%
Total revenue	—	10,000,000	(10,000,000)	(100)%
Operating expenses:				
General and administrative	2,920,672	2,792,894	127,778	5 %
Research and development	6,043,684	6,797,784	(754,100)	(11)%
License fee expenses	25,000	25,000	—	— %
Total operating expenses	8,989,356	9,615,678	(626,322)	(7)%
Income (loss) from operations	(8,989,356)	384,322	(9,373,678)	(2439)%
Other income	227,124	29,676	197,448	665 %
Net income (loss)	$ (8,762,232)	$ 413,998	$ (9,176,230)	(2216)%
Other comprehensive income (loss):				
Foreign currency translation adjustments	(31,151)	(135,869)	104,718	(77)%
Comprehensive income (loss)	$ (8,793,383)	$ 278,129	$ (9,071,512)	(3262)%

Revenues

License fee revenue for the three months ended June 30, 2022 relates to our license agreement with Organon to commercialize XACIATO. We earned $10.0 million in license fee revenue related to the transfer of the license and related know-how to Organon upon effectiveness of the agreement on June 30, 2022.

General and administrative expenses

The increase of approximately $128,000 in general and administrative expenses for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 was primarily attributable to increases in (i) professional services expense of approximately $148,000, (ii) personnel costs of approximately $104,000, and (iii) stock-based compensation expense of approximately $74,000. These increases were partially offset by decreases in general corporate overhead, including rent and facilities expenses, of approximately $158,000.

Research and development expenses

The decrease of approximately $754,000 in research and development expenses for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 was primarily attributable to decreases in expenses related to our Sildenafil Cream Phase 2b RESPOND clinical study of approximately $1.2 million, and decreases in expenses related to clinical trial and manufacturing and regulatory affairs activities for our clinical-stage product candidate Ovaprene of approximately $831,000, partially offset by increases in costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $1.3 million.

License fee expenses

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

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

Other income

The increase of $0.2 million in other income for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 was primarily due to an increase in interest earned on cash balances in the current period.

Comparison of Six Months Ended June 30, 2023 and 2022 (Unaudited)

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

	Six Months Ended June 30,		Change	
	2023	2022	$	%
Revenues:				
License fee revenue	$ —	$ 10,000,000	$ (10,000,000)	100 %
Total revenue	—	10,000,000	(10,000,000)	100 %
Operating expenses:				
General and administrative	6,258,098	5,362,881	895,217	17 %
Research and development	11,063,907	12,603,247	(1,539,340)	(12)%
License fee expenses	50,000	50,000	—	— %
Total operating expenses	17,372,005	18,016,128	(644,123)	(4)%
Loss from operations	(17,372,005)	(8,016,128)	(9,355,877)	117 %
Other income	567,272	31,456	535,816	1703 %
Net loss	$ (16,804,733)	$ (7,984,672)	$ (8,820,061)	110 %
Other comprehensive loss:				
Foreign currency translation adjustments	(53,156)	(145,019)	91,863	(63)%
Comprehensive loss	$ (16,857,889)	$ (8,129,691)	$ (8,728,198)	107 %

Revenues

License fee revenue relates to our license agreement with Organon to commercialize XACIATO. See "*—Comparison of Three Months Ended June 30, 2023 and 2022 (Unaudited)—Revenues*," above.

General and administrative expenses

The increase of approximately $895,000 in general and administrative expenses for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022 was primarily attributable to (i) a one-time fraud loss of approximately $230,000, net of proceeds we received under an insurance policy, related to criminal fraud commonly referred to as "business email compromise fraud" to which we were subject, and (ii) increases in (a) professional services expense of approximately $226,000, (b) commercial-readiness expenses of approximately $199,000, (c) personnel costs of approximately $153,000, and (d) stock-based compensation expense of approximately $141,000. These increases were partially offset by decreases in general corporate overhead, including rent and facilities expenses, of approximately $54,000.

Research and development expenses

The decrease of approximately $1.5 million in research and development expenses for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022 was primarily attributable to decreases in (i) expenses related to clinical trial and manufacturing and regulatory affairs activities for our clinical-stage product candidate Ovaprene of approximately $1.9 million, (ii) costs related to our Sildenafil Cream exploratory Phase 2b RESPOND clinical study of approximately $1.5 million, and (iii) costs related to our pre-clinical development activities of approximately $219,000, partially offset by increases in costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $2.1 million.

License fee expenses

For each of the six months ended June 30, 2023 and June 30, 2022, we accrued $50,000 of the $100,000 annual license maintenance fee payable under our license agreement related to DARE-HRT1.

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

Other income

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

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

At June 30, 2023, our accumulated deficit was approximately $157.9 million, our cash and cash equivalents were approximately $13.3 million, our deferred grant funding liabilities under our grant agreements related to DARE-LARC1 and DARE-LBT were approximately $13.1 million and $0.6 million, respectively, and our working capital deficit was approximately $2.5 million. Substantially all of our cash and cash equivalents at June 30, 2023 represented funds received under such grant agreements and such funds may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. We incurred a loss from operations of approximately $16.8 million and had negative cash flow from operations of approximately $22.7 million during the six months ended June 30, 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, and in particular, if we determine to engage in commercialization activities directly as opposed to through a third-party collaborator. 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. In large part, we can control the pace of advancement of our development programs and, therefore, we can control the timing of when we incur most of our research and development expenses.

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

We anticipate our general and administrative expenses to increase in 2023 compared to 2022 primarily due to increased personnel costs and other general corporate overhead. General and administrative expenses have included and are expected to include additional 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 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. The amount of our research and development expenses for the remainder of 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. We currently anticipate our research and development expenses for 2023 will be less than our research and development expenses for 2022, in part due to cost-savings measures we have implemented. Our research and development expenses for the remainder of 2023 will be primarily associated with our exploratory Phase 2b RESPOND clinical study and ongoing Phase 1 thermography clinical study of Sildenafil Cream, 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 the majority of such expenses we can control.

We closely monitor our cash resources and we have implemented cost-savings measures, primarily by controlling our spend on research and development activities related to clinical-stage programs other than Ovaprene and Sildenafil Cream. These cost-savings measures may impact anticipated development timelines for our clinical-stage programs, including DARE-HRT1, DARE-VVA1 and DARE-204/214. We will need additional capital to fund our operating needs into the fourth quarter of 2023 and to meet our current obligations as they become due. We are in ongoing discussions with multiple potential third-party sources of additional capital, including non-dilutive sources of capital, 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 when needed, on favorable terms, or at all. If we cannot raise capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. See the risk factor in Item 1A of Part II of this report titled, *We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.*

Historically, the cash used to fund our operations has come from a variety of sources and predominantly from sales of shares of our common stock. We have also received a significant amount of cash through non-dilutive grants and strategic collaborations. We will continue to evaluate and may pursue a variety of capital raising options on an on-going basis, including sales of equity (including sales of our common stock in ATM offerings), debt financings, government or other grant funding, collaborations, structured financings, and strategic alliances or other similar types of arrangements, to cover our operating expenses, and the cost of any license or other acquisition of new product candidates or technologies. There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders. Our ability to raise capital through sales of our common stock will depend on a variety of factors including, among others, market conditions, the trading price and volume of our common stock, our clinical and commercial developments, and investor sentiment. In addition, macroeconomic factors and volatility in the financial market, which may be exacerbated in the short term by concerns over inflation, rising interest rates, economic recession, adverse developments affecting financial institutions or the financial services industry, impacts of the 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.

We prepared the accompanying condensed consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. As discussed above, there is substantial doubt about our ability to continue as a going concern because we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

Cash Flows

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

	Six months ended June 30,	
	2023	**2022**
Net cash used in operating activities	$ (22,703,918)	$ (20,791,986)
Net cash used in investing activities	—	(5,369)
Net cash provided by financing activities	1,751,570	1,338,899
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(53,156)	(145,019)
Net decrease in cash, cash equivalents and restricted cash	$ (21,005,504)	$ (19,603,475)

Net cash used in operating activities

Cash used in operating activities for the six months ended June 30, 2023 included the net loss of $16.8 million, decreased by non-cash stock-based compensation expense of approximately $1.3 million. Components providing operating cash were an increase in accounts payable of approximately $4.5 million, a decrease in other receivables of approximately $1.1 million, and an increase in deferred revenue of approximately $0.2 million related to XACIATO commercial product supply. Components reducing operating cash were a decrease in accrued expenses of approximately $6.7 million, a decrease in deferred grant funding of approximately $4.6 million, an increase in prepaid expenses of approximately $1.4 million, and a one-time fraud loss of $0.2 million related to a "business email compromise fraud" to which we were subject, net of insurance reimbursement, which was recognized in general and administrative expenses.

Cash used in operating activities for the six months ended June 30, 2022 included the net loss of $8.0 million, decreased by non-cash stock-based compensation expense of approximately $1.1 million. A component providing operating cash was an increase in accrued expenses of approximately $3.2 million. Components reducing operating cash were an increase in accounts receivable of $10.0 million related to our exclusive license agreement for XACIATO, an increase in prepaid expenses of approximately $3.4 million, a decrease in deferred grant funding of approximately $1.8 million, an increase in other receivables of approximately $1.0 million, and a decrease in accounts payable of approximately $1.0 million.

Net cash used in investing activities

No cash was used in investing activities for the six months ended June 30, 2023. Net cash used in investing activities for the six months ended June 30, 2022 was de minimis.

Net cash provided by financing activities

Cash provided by financing activities for the six months ended June 30, 2023 and June 30, 2022 of approximately $1.8 million and $1.2 million in the aggregate, respectively, primarily consisted of sales of our common stock under our ATM sales agreement and upon the exercise of warrants.

License and Royalty Agreements

We agreed to make royalty and milestone payments under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream, and under other agreements related to our other clinical and preclinical candidates. During the remainder of 2023, based on our current expectations regarding the development of our product candidates and sales of XACIATO, we expect to pay approximately $2.7 million in royalty and milestone payments under the license and development agreements, which is significantly less than our previously reported expected amount, primarily due to lesser anticipated royalty payments we may owe with respect to sales of XACIATO resulting from the delay of its commercial launch from earlier expectations. 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 June 30, 2023 at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. As of the date of filing this report, there is no material pending legal proceeding to which we are a party or to which any of our property is subject, and management is not aware of any contemplated proceeding by any governmental authority against us.

Item 1A. Risk Factors

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

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

We have a history of losses from operations, we expect negative cash flows from our operations to continue for the foreseeable future, and we expect that our net losses will continue for the foreseeable future as we develop and seek to bring to market our existing product candidates and as we seek to potentially acquire or license and develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2022 and June 30, 2023 were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. At June 30, 2023, our accumulated deficit was approximately $157.9 million, our cash and cash equivalents were approximately $13.3 million, our deferred grant funding liabilities under our grant agreements related to DARE-LARC1 and DARE-LBT were approximately $13.7 million, and we had a working capital deficit of approximately $2.5 million. Substantially all of our cash and cash equivalents at June 30, 2023 represented funds received under such grant agreements and such funds may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. We will require additional capital to fund our operating needs into the fourth quarter of 2023 and to meet our current obligations as they become due. Advancing our investigational women's health products through clinical development and pursuing regulatory approval and commercialization will require substantial additional investment. We will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. The amount and timing of our capital needs have and will continue to depend highly on many factors, as discussed further below as well as under "ITEM 2. MANAGEMENT'S DISCUSSION OF AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS—Liquidity and Capital Resources—Plan of Operations and Future Funding Requirements" in Part I of this report.

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

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

- the product development programs we choose to pursue;
- the cost and pace of preclinical and clinical development;

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

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

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

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

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

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

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

In addition, the Nasdaq Capital Market requires that companies have: (x) stockholders' equity of at least $2.5 million; (y) a market value of listed securities of at least $35 million; or (z) net income from continuing operations of $500,000 in the company's most recently completed fiscal year or in two of the three most recently completed fiscal years. Our stockholders' equity at June 30, 2023 was negative $2.7 million and we do not currently meet either of the two alternative compliance standards described in clause (y) and (z). Accordingly, we expect to receive a separate notice from Nasdaq informing us that we do not meet the foregoing continued listing requirements. If we receive such a notice, we expect to be afforded 45 days to submit a plan to regain compliance with the stockholders' equity requirement for Nasdaq's consideration, and if the plan is accepted, to be granted an extension period of up to 180 calendar days from the date of the deficiency notice to regain compliance. If the plan is not accepted or if we are unable to regain compliance within any extension period granted by Nasdaq, Nasdaq would be required to issue a delisting determination, which we expect we would be entitled to request a hearing before a Nasdaq Hearings Panel to present a plan to regain compliance and to request a further extension period to regain compliance.

There can be no assurance we will regain compliance with the Minimum Bid Price Requirement or continue to satisfy the other continued listing requirements of The Nasdaq Capital Market. The delisting of our common stock, or the commencement of delisting proceedings, for whatever reason could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the suspension or delisting of our common stock, or the commencement of delisting proceedings, for whatever reason may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

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

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
3.1	Third Amended and Restated Bylaws					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

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: August 10, 2023

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

Date: August 10, 2023

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

THIRD AMENDED AND RESTATED BY-LAWS

OF

DARÉ BIOSCIENCE, INC.

(as amended through January 24, 2023)

TABLE OF CONTENTS

ARTICLE I
STOCKHOLDERS

I Place of Meetings. All meetings of stockholders shall be held at such place as may be designated from time to time by the Board of Directors, the Chair of the Board, the Chief Executive Officer or the President or, if not so designated, at the principal office of the corporation. The Board of Directors may, in its sole discretion, determine that any meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized under General Corporation Law of the State of Delaware (the "DGCL").

1.1 Annual Meeting. The annual meeting of stockholders for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly be brought before the meeting shall be held on a date and at a time designated by the Board of Directors, the Chair of the Board, the Chief Executive Officer or the President (which date shall not be a legal holiday in the place where the meeting is to be held).

1.2 Special Meetings. Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chair of the Board or the Chief Executive Officer, and may not be called by any other person or persons. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

1.3 Notice of Meetings.

(a) Except as otherwise provided by law, notice of each meeting of stockholders, whether annual or special, shall be delivered by the corporation to each stockholder entitled to vote at such meeting not less than 10 nor more than 60 days before the date of the meeting, either personally, by mail, by courier service, or, in accordance with any applicable requirements of the DGCL, by electronic transmission (as such term is defined in the DGCL). Without limiting the manner by which notice otherwise may be given to stockholders, any written, printed, or electronic notice of all meetings shall state the place, if any, date and time of the meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting), and shall specify the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at any such meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called.

(b) If notice is given by mail, such notice shall be deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. If notice is delivered by courier service, such notice shall be deemed given on the earlier of when the notice is received or left at the stockholder's address. If notice is delivered by electronic mail (as such term is defined in the DGCL), such notice shall be deemed given when directed to such stockholder's electronic mail address (unless the stockholder has notified the corporation in writing or by electronic transmission of an objection to receiving notice by electronic mail or such notice is prohibited by the DGCL to be given by electronic transmission). A notice by electronic mail must include a prominent legend that the communication is an important notice regarding the corporation, and will be deemed to include any files attached thereto and any information hyperlinked to a website if such electronic mail includes the contact information of an officer or agent of the corporation who is available to assist with accessing such files or information. Notice given by electronic transmission (other than electronic mail) shall be effective if it is given by a form of electronic transmission consented to by the stockholder (in a manner consistent with the DGCL) to whom the notice is directed. Such notice shall be deemed given at the time specified in Section 232 of the DGCL.

(c) Whenever any notice is required to be given to any stockholder under the provisions of the DGCL or these amended By-laws, a waiver thereof in writing, signed by the person or persons entitled to such notice, or a waiver by electronic transmission by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

1.4 Voting List. The corporation shall prepare, no later than the 10th day before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in

alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of 10 days ending on the day before the meeting date: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. The list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

1.5 Quorum. Except as otherwise provided by law, the Certificate of Incorporation or these By-laws, the holders of a majority in voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of capital stock is required by law or the Certificate of Incorporation, the holders of a majority in voting power of the shares of such class or classes or series of the capital stock of the corporation issued and outstanding and entitled to vote on such matter, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

1.6 Adjournments. Any meeting of stockholders may be adjourned from time to time to any other time and to any other place at which a meeting of stockholders may be held under these By-laws (including an adjournment taken to address a technical failure to convene or continue a meeting using remote communication), by the chair of the meeting or by the stockholders present or represented at the meeting and entitled to vote, although less than a quorum. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time, place, date, and means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting are (i) announced at the meeting at which the adjournment is taken; (ii) displayed, during the time scheduled for the meeting, on the same electronic network used to enable stockholders and proxyholders to participate in the meeting by means of remote communication; or (iii) provided in any other manner permitted by the DGCL. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in accordance with the DGCL, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

1.7 Voting and Proxies.

(a) Each stockholder shall have one vote for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided by law or the Certificate of Incorporation.

(b) Each stockholder of record entitled to vote at a meeting of stockholders may vote in person (including by means of remote communications, if any, by which stockholders may be deemed to be present in person and vote at such meeting) or may authorize another person or persons to vote for such stockholder by a proxy executed or transmitted in a manner permitted by the DGCL by the stockholder or such stockholder's authorized agent and delivered (including by electronic transmission) to the Secretary of the corporation. No such proxy shall be voted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.

(c) Any stockholder directly or indirectly soliciting proxies from other stockholders must use a form of appointment of proxy (i.e., a proxy card) that is a color other than white. A white-colored proxy card shall be reserved for the exclusive use by the Board of Directors.

1.8 Action at Meeting. When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting shall be decided by the vote of the holders of shares of stock having a majority in voting power of the votes cast by the holders of all of the shares of stock present or represented at the meeting and voting affirmatively or negatively on such matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each such class or series, the holders of a majority in voting power of the shares of stock of that class or series present or represented at the meeting and voting affirmatively or negatively on such matter), except when a different or minimum vote is required by any law applicable to the corporation or its securities, the Certificate of Incorporation or these By-laws, in which case such different or minimum vote shall be the applicable vote on the matter. When a quorum is present at any meeting, any election by stockholders of directors shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

1.9 Nomination of Directors.

(a) Generally. Except for (1) any directors entitled to be elected by the holders of preferred stock, (2) any directors elected in accordance with Section 2.9 hereof by the Board of Directors to fill a vacancy or newly-created directorship or (3) as otherwise required by applicable law or stock exchange regulation, at any meeting of stockholders, only persons who are nominated in accordance with this Section 1.10 shall be eligible to be elected as directors at an annual or special meeting of stockholders.

(b) Nominations of Candidates. Nominations of any person for election to the Board of Directors at an annual meeting or special meeting of the stockholders of the corporation (but, with respect to a special meeting, only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (i) by or at the direction of the Board of Directors, including by any committee or persons authorized to do so by the Board of Directors or these By-laws, or (ii) by a stockholder present in person who (A) was a stockholder of record of the corporation both at the time of giving the notice provided for in this Section 1.10 and at the time of the meeting, (B) is entitled to vote at the meeting, and (C) has complied with this Section 1.10 and Section 1.11 with respect to such notice and nomination. The foregoing clause (ii) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board of Directors at an annual meeting or special meeting of the stockholders of the corporation.

For purposes of this Section 1.10, “present in person” shall mean that the stockholder proposing to nominate one or more candidates for election to the Board of Directors at the meeting, or a qualified representative of such stockholder, appears in person at such meeting if such meeting is held solely at a physical location or, in the event that such meeting permits stockholder attendance by means of remote communication, appears by such means of remote communication; a “qualified representative” of such proposing stockholder shall be a duly authorized officer, manager or partner of such stockholder or any other person authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must provide such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, to the Secretary of the corporation prior to or at the time of the meeting of stockholders. For the avoidance of doubt, notwithstanding anything to the contrary in these By-laws, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) nominating a candidate for election as a director at a meeting is not present in person at the meeting, such candidate shall not be considered for election as a director, and any proxies or votes cast in favor of or for the election of such candidate shall be disregarded (provided, however, that such proxies and/or votes will be counted for the purposes of establishing a quorum).

(c) Stockholder Advance Notice.

(i) For a stockholder to make any nomination of a person or persons for election to the Board of Directors at an annual meeting of the stockholders of the corporation, the stockholder must (1) provide Timely Notice (as defined below) thereof in writing and in proper form to the Secretary of the corporation, (2) provide the information, agreements and questionnaires with respect to such stockholder and its candidate(s) for nomination as required to be set forth by this Section 1.10 and Section 1.11 and (3) provide any updates or supplements to such notice at the times and in the forms required by this Section 1.10 and Section 1.11. To be timely, a stockholder’s notice

must be received in writing by the Secretary of the corporation at the principal executive offices of the corporation not later than the close of business on the 90th day or earlier than the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is advanced by more than 20 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (A) the 90th day prior to such annual meeting and (B) the 10th day following the day on which public disclosure (as defined below) of the date of such annual meeting is first made (such notice within such time periods, "Timely Notice"). In no event shall the adjournment, recess, postponement, judicial stay or rescheduling of an annual meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of Timely Notice as described above. For purposes of these By-laws, "public disclosure" means disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

(ii) If the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling a special meeting of the stockholders of the corporation, then for a stockholder to make any nomination of a person or persons for election to the Board of Directors at such special meeting, the stockholder must (i) provide Timely Notice thereof in writing and in proper form to the Secretary of the corporation at the principal executive offices of the corporation, (ii) provide the information with respect to such stockholder and its candidate(s) for nomination as required by this Section 1.10 and Section 1.11 and (iii) provide any updates or supplements to such notice at the times and in the forms required by this Section 1.10. To be timely, a stockholder's notice for nominations to be made at such special meeting must be received in writing by the Secretary of the corporation at the principal executive offices of the corporation not earlier than the 120th day prior to such special meeting and not later than the close of business on the later of (x) the 90th day prior to such special meeting and (y) the 10th day following the day on which public disclosure of the date of such special meeting was first made (solely for purposes of special meetings of stockholders of the corporation, the term "Timely Notice" shall mean such notice within the time periods set forth in this sentence). In no event shall the adjournment, recess, postponement, judicial stay or rescheduling of a special meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of Timely Notice as described above.

(iii) In no event may a Nominating Person (as defined below) provide Timely Notice with respect to a greater number of director candidates than are subject to election by stockholders at the applicable meeting. If the corporation shall, subsequent to such notice, increase the number of directors subject to election at the meeting, such notice as to any additional nominees shall be due on the later of (A) the conclusion of the time period for Timely Notice, (B) the date set forth in 1.10(c)(ii) or (C) the 10th day following the date of public disclosure of such increase.

(d) Contents of Notice. To be in proper form for purposes of this Section 1.10, a stockholder's notice to the Secretary of the corporation shall set forth:

(i) As to each Nominating Person, (A) the name and address of such Nominating Person (including, if applicable, the name and address that appear on the corporation's books and records) and (B) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by each Nominating Person (specifying the type of ownership for the class and/or series and the number of shares of stock of the corporation that are, directly or indirectly, owned of record or beneficially owned by each Nominating Person), except that such Nominating Person shall in all events be deemed to beneficially own any shares of any class or series of the corporation as to which such Nominating Person has a right to acquire beneficial ownership at any time in the future;

(ii) As to each Nominating Person, (A) the full notional amount of any securities that, directly or indirectly, underlie any "derivative security" (as such term is defined in Rule 16a-1(c) under the Exchange Act) that constitutes a "call equivalent position" (as such term is defined in Rule 16a-1(b) under the Exchange Act) ("Synthetic Equity Position") and that is, directly or indirectly, held or maintained by such Nominating Person with respect to any shares of any class or series of shares of the corporation; provided that, for the purposes of the definition of "Synthetic Equity Position," the term "derivative security" shall also include any security or instrument that would not otherwise

constitute a “derivative security” as a result of any feature that would make any conversion, exercise or similar right or privilege of such security or instrument becoming determinable only at some future date or upon the happening of a future occurrence, in which case the determination of the amount of securities into which such security or instrument would be convertible or exercisable shall be made assuming that such security or instrument is immediately convertible or exercisable at the time of such determination; and, provided, further, that any Nominating Person satisfying the requirements of Rule 13d-1(b)(1) under the Exchange Act (other than a Nominating Person that so satisfies Rule 13d-1(b)(1) under the Exchange Act solely by reason of Rule 13d-1(b)(1)(ii)(E)) shall not be deemed to hold or maintain the notional amount of any securities that underlie a Synthetic Equity Position held by such Nominating Person as a hedge with respect to a bona fide derivatives trade or position of such Nominating Person arising in the ordinary course of such Nominating Person’s business as a derivatives dealer, (B) any rights to dividends on the shares of any class or series of shares of the corporation owned beneficially by such Nominating Person that are separated or separable from the underlying shares of the corporation, (C) any material pending or threatened legal proceeding in which such Nominating Person is a party or material participant involving the corporation, any affiliate of the corporation, or any of their respective officers or directors, (D) any other material relationship between such Nominating Person, on the one hand, and the corporation, any affiliate of the corporation, or any of their respective officers or directors, on the other hand, (E) any direct or indirect material interest in any material contract or agreement of such Nominating Person with the corporation or any affiliate of the corporation (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), and (F) any other information relating to such Nominating Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with the election of directors by such Nominating Person pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (E) are referred to as “Disclosable Interests”); provided, however, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Nominating Person solely as a result of being the stockholder of record directed to prepare and submit the notice required by these By-laws on behalf of a beneficial owner;

(iii) As to each Nominating Person, a reasonably detailed description of all agreements, arrangements and understandings (A) between or among any of the Nominating Persons and (B) between or among any Nominating Person and any other person or entity (including their names) in connection with the nomination of such candidate; provided, however, that the disclosures required by this paragraph (iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Nominating Person solely as a result of being the stockholder of record directed to prepare and submit the notice required by these By-laws on behalf of a beneficial owner;

(iv) As to each Nominating Person, a representation that the Nominating Person will or is part of a group that will (A) solicit proxies from holders of the corporation’s outstanding capital stock representing at least 67% of the voting power of shares of capital stock entitled to vote on the election of directors, (B) include a statement to that effect in its proxy statement and/or its form of proxy, (C) otherwise comply with Rule 14a-19 under the Exchange Act and (D) provide the Secretary of the corporation not less than five business days prior to the applicable meeting, or any adjournment or postponement thereof, with reasonable documentary evidence that such Nominating Person complied with such representations; and

(v) As to each candidate whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such candidate for nomination that would be required to be set forth in a stockholder’s notice pursuant to this Section 1.10 and Section 1.11 if such candidate for nomination were a Nominating Person, (B) all information relating to such candidate for nomination that is required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including such candidate’s written consent to being named in any proxy statement for the applicable meeting and any associated proxy card as a nominee and to serving as a director if elected), (C) a description of any direct or indirect material interest in any material contract or agreement between or among any Nominating Person, on the one hand, and each candidate for nomination or his or her respective associates or any other participants in such solicitation, on the other hand, including, without limitation, all information that would be required to be

disclosed pursuant to Item 404 under Regulation S-K of the SEC if such Nominating Person were the "registrant" for purposes of such Item 404 and the candidate for nomination were a director or executive officer of such registrant (the disclosures to be made pursuant to the foregoing clauses (A) through (C) are referred to as "Nominee Information"), and (D) a completed and signed questionnaire, representation and agreement as required by Section 1.11(a).

For purposes of this Section 1.10, the term "Nominating Person" shall mean (i) the stockholder providing the notice of the nomination proposed to be made at the meeting of the stockholders of the corporation, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, and (iii) any participant (as defined in paragraphs (a)(ii)-(vi) of Instruction 3 to Item 4 of Schedule 14A under the Exchange Act) with such stockholder in such solicitation.

(e) Updating of Notice. A stockholder providing notice of any nomination proposed to be made at a meeting of the stockholders of the corporation shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 1.10 shall be true and correct as of the record date for stockholders entitled to vote at such meeting and as of the date that is 10 business days prior to the date of such meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary of the corporation at the principal executive offices of the corporation (or any other office specified by the corporation in any public disclosure) not later than five business days after the record date for stockholders entitled to vote at such meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight business days prior to the date for such meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of 10 business days prior to such meeting or any adjournment or postponement thereof). Notwithstanding the foregoing, if a Nominating Person no longer intends to solicit proxies pursuant to Section 1.10(d)(iv), such Nominating Person shall inform the corporation of this change by delivering a writing to the Secretary of the corporation at the principal executive offices of the corporation (or any other office specified by the corporation in any public disclosure) no later than two business days after the occurrence of such change. For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these By-laws shall not limit the corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any nomination or to submit any new nomination.

(f) Required Compliance with the Exchange Act. In addition to the requirements of this Section 1.10 with respect to any nomination proposed to be made at a meeting of the stockholders of the corporation, each Nominating Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations. Notwithstanding the foregoing provisions of this Section 1.10, unless otherwise required by law, (i) no Nominating Person shall solicit proxies in support of the election of director nominees at such meeting other than the Board of Directors' nominees unless such Nominating Person has complied with Rule 14a-19 under the Exchange Act in connection with the solicitation of such proxies with respect to such meeting, including the provision to the corporation of notices required thereunder in a timely manner and (ii) if any Nominating Person (1) provides notice pursuant to Rules 14a-19(a)(1) and (b) under the Exchange Act and (2) subsequently fails to comply with the requirements of Rule 14a-19 under the Exchange Act (including the provision to the corporation of notices required thereunder in a timely manner and evidence that the Nominating Person on whose behalf a nomination is made complied with such Nominating Person's representation as to whether the Nominating Person solicited (or is part of a group which solicited) proxies in support of such nomination as required by clause (A) of Section 1.10(d)(iv)), then the corporation shall disregard any proxies or votes solicited for the Nominating Person's candidates, notwithstanding that proxies or votes with respect to such nominations may have been received by the corporation (provided, however, that such proxies and/or votes will be counted for the purposes of establishing a quorum).

(g) Means of Delivery. Any written notice, supplement, update or other information required to be delivered to the corporation pursuant to this Section 1.10 must be given by personal delivery, by overnight courier or by registered or certified mail, postage prepaid, to the Secretary at the corporation's principal executive offices.

1.10 Additional Requirements for Valid Nomination of Candidates to Serve as Director and, if Elected, to be Seated as Directors.

(a) Candidate to Provide Questionnaire, Representation and Agreement. To be eligible to be a candidate for election as a director of the corporation at an annual meeting or special meeting of the stockholders of the corporation, a candidate must be nominated in the manner prescribed in Section 1.10 and a candidate nominated by a stockholder must have previously delivered (in accordance with the time period prescribed for delivery in a notice to such candidate given by or on behalf of the Board of Directors), to the Secretary of the corporation at the principal executive offices of the corporation, (i) a completed written questionnaire with respect to the background, qualifications, stock ownership and independence of such proposed nominee and the background of any other person or entity on whose behalf the nomination is being made (which questionnaire shall be provided by the corporation upon written request of a stockholder therefor) and (ii) a written representation and agreement (in a form provided by the corporation upon written request of a stockholder therefor) that such candidate for nomination (A) is not and will not become a party to any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the corporation, will act or vote on any issue or question if such agreement, arrangement or understanding has not been disclosed to the corporation, or if such agreement, arrangement or understanding could limit or interfere with such person's ability to comply, if elected as a director of the corporation, with such person's fiduciary duties under applicable law, (B) may not be, and may not become, a party to any compensatory, payment, indemnification or other financial agreement, arrangement or understanding with any person or entity other than the corporation in connection with service or action as a director that has not been disclosed to the corporation, and (C) will comply with all of the corporation's corporate governance, conflict of interest, confidentiality, and stock ownership and trading policies and guidelines, and any other corporation policies and guidelines applicable to directors (and, if requested by any candidate for nomination, the Secretary of the corporation shall provide to such candidate for nomination all such policies and guidelines then in effect).

(b) Candidate to Furnish Certain Other Information. The corporation may request such additional information as necessary to permit the Board of Directors to determine if each candidate for election as a director of the corporation is independent under any applicable listing standards, any applicable rules of the SEC and any publicly disclosed standards used by the Board of Directors in determining and disclosing the independence of the corporation's directors.

(c) Updating Candidate Information. A candidate for nomination as a director shall further update and supplement the materials delivered pursuant to this Section 1.11, if necessary, so that the information provided or required to be provided pursuant to this Section 1.11 shall be true and correct as of the record date for stockholders entitled to vote at the meeting and as of the date that is 10 business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary of the corporation at the principal executive offices of the corporation (or any other office specified by the corporation in any public disclosure) not later than five business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these By-laws shall not limit the corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or to submit any new proposal, including by changing or adding nominees, matters, business or resolutions proposed to be brought before a meeting of the stockholders.

(d) Rejection of Nominee for Non-compliance. No candidate shall be eligible for nomination as a director of the corporation, or be seated as a director, unless such candidate and the Nominating Person seeking to place such candidate's name in nomination has complied with Section 1.10 and with this Section 1.11. The chair of the meeting shall, if the facts warrant, determine that a

nomination was not properly made in accordance with Section 1.10 and with this Section 1.11, and if he or she should so determine, he or she shall so declare such determination to the meeting and the defective nomination shall be disregarded, notwithstanding that proxies or votes in respect of such nomination may have been received by the corporation (provided, however, that such proxies and/or votes will be counted for the purposes of establishing a quorum).

1.11 Business at Annual Meetings Other than Election of Directors.

(a) Generally. At any annual meeting of the stockholders of the corporation, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting of the stockholders of the corporation, business must be (i) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (ii) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (iii) properly brought before the meeting by a stockholder of the corporation present in person who (A) (1) was a stockholder of record of the corporation both at the time of giving the notice provided for in this Section 1.12 and at the time of the meeting, (2) is entitled to vote at the meeting, and (3) has complied with this Section 1.12 in all applicable respects or (B) properly made such proposal in accordance with Rule 14a-8 under the Exchange Act. The foregoing clause (iii) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders of the corporation. Stockholders seeking to nominate persons for election to the Board of Directors must comply with Section 1.10 and Section 1.11, and this Section 1.12 shall not be applicable to such nominations. Furthermore, for any business to be properly brought before the meeting by a stockholder, such business must constitute a proper matter under Delaware law for stockholder action.

For purposes of this Section 1.12, “present in person” means that the stockholder proposing that the business be brought before the annual meeting of the stockholders of the corporation, or a qualified representative of such proposing stockholder, appears in person at such annual meeting if the annual meeting of the stockholders of the corporation is held solely at a physical location or, in the event that the annual meeting permits stockholder attendance by means of remote communication, appears by such means of remote communication; and a “qualified representative” of such proposing stockholder shall be a duly authorized officer, manager or partner of such stockholder or any other person authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the annual meeting of stockholders and such person must provide such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, to the Secretary of the corporation prior to or at the time of such annual meeting. For the avoidance of doubt, notwithstanding anything to the contrary in these By-laws, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) proposing business to be conducted at a meeting is not present in person at the annual meeting, such business shall not be considered, and no vote shall be taken with respect to such proposed business, notwithstanding that proxies in respect of such business may have been received by the corporation.

(b) Timeliness of Notice. For business to be properly brought before an annual meeting of the stockholders of the corporation by a stockholder, the stockholder must (i) provide Timely Notice (as defined in Section 1.10) thereof in writing and in proper form to the Secretary of the corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 1.12. In no event shall the adjournment, recess, postponement, judicial stay or rescheduling of an annual meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of Timely Notice.

(c) Contents of Notice. To be in proper form for purposes of this Section 1.12, a stockholder’s notice to the Secretary of the corporation shall set forth:

(i) As to each item of business that the Proposing Person (as defined below) proposes to bring before such annual meeting: (A) a brief description of the business desired to be brought before the annual meeting, (B) the text of the proposal or business (including the exact text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the By-laws, the exact text of the proposed amendment), (C) the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (D) a reasonably detailed description of all agreements, arrangements and understandings (x) between or among any of the Proposing Persons or (y) between or among any Proposing Person and any other

person or entity (including their names) in connection with the proposal of such business by the Proposing Persons and (E) all other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; provided, however, that the disclosures required by this paragraph (i) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder of record directed to prepare and submit the notice required by these By-laws on behalf of a beneficial owner;

(ii) As to each Proposing Person, (A) the name and address of such Proposing Person (including, if applicable, the name and address that appear on the corporation's books and records); and (B) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by each Proposing Person (specifying the type of ownership for the class and/or series and the number of shares of stock of the corporation that are, directly or indirectly, owned of record or beneficially owned by each Proposing Person), except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future; and

(iii) As to each Proposing Person, (A) any Disclosable Interests (as defined in Section 1.10(d)(ii), except that for purposes of this Section 1.12, the term "Proposing Person" shall be substituted for the term "Nominating Person" in all places it appears in Section 1.10(d)(ii))), (B) a representation that such Proposing Person intends or is part of a group that intends to deliver a proxy statement or form of appointment of proxy to holders of at least the percentage of the corporation's outstanding capital stock required to approve or adopt the proposal or otherwise solicit proxies from stockholders in support of such proposal, and (C) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act.

For purposes of this Section 1.12, the term "Proposing Person" shall mean (i) the stockholder providing the notice of business proposed to be brought before an annual meeting of stockholders of the corporation, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before such annual meeting is made, and (iii) any participant (as defined in paragraphs (a)(ii)-(vi) of Instruction 3 to Item 4 of Schedule 14A under the Exchange Act) with such stockholder in such solicitation.

(d) Required Updating of Notice. A Proposing Person shall update and supplement its notice to the corporation of its intent to propose business at an annual meeting of stockholders of the corporation, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 1.12 shall be true and correct as of the record date for stockholders entitled to vote at such annual meeting and as of the date that is 10 business days prior to such annual meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary of the corporation at the principal executive offices of the corporation (or any other office specified by the corporation in any public disclosure) not later than five business days after the record date for stockholders entitled to vote at such annual meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight business days prior to the date for such annual meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which such annual meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of 10 business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these By-laws shall not limit the corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or to submit any new proposal, including by changing or adding matters, business or resolutions proposed to be brought before a meeting of the stockholders.

(e) Requirement for Compliance. Notwithstanding anything in these By-laws to the contrary, no business shall be conducted at an annual meeting of the stockholders of the corporation that is not properly brought before such annual meeting in accordance with this Section 1.12. The chair

of any annual meeting of stockholders of the corporation shall have the power and duty to determine whether business was properly brought before the annual meeting in accordance with the provisions of this Section 1.12 (including whether the Proposing Person solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in support of such Proposing Person's proposal in compliance with the representation with respect thereto required by this Section 1.12), and if the chair should determine that business was not properly brought before the annual meeting in accordance with the provisions of this Section 1.12, the chair shall so declare to the meeting and such business shall not be brought before the annual meeting, in each case, notwithstanding that proxies or votes with respect to such business may have been received by the corporation (provided, however, that such proxies and/or votes will be counted for the purposes of establishing a quorum).

(f) Applicability. This Section 1.12 is expressly intended to apply to any business proposed to be brought before an annual meeting of the stockholders of the corporation other than any proposal made in accordance with Rule 14a-8 under the Exchange Act and included in the corporation's proxy statement. In addition to the requirements of this Section 1.12 with respect to any business proposed to be brought before an annual meeting of stockholders of the corporation, each Proposing Person shall comply with all applicable requirements of state law and of the Exchange Act, and the rules and regulations thereunder, with respect to any such business. Nothing in this Section 1.12 shall be deemed to affect the rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

(g) Other. Except as otherwise required by law, nothing in this Section 1.12 shall obligate the corporation or the Board of Directors to include in any proxy statement (or other stockholder communication distributed on behalf of the corporation or the Board of Directors) information with respect to any proposal submitted by a stockholder.

(h) Means of Delivery. Any written notice, supplement, update or other information required to be delivered to the corporation pursuant to this Section 1.12 must be given by personal delivery, by overnight courier or by registered or certified mail, postage prepaid, to the Secretary of the corporation at the corporation's principal executive offices.

1.12 Conduct of Meetings.

(a) Meetings of stockholders of the corporation shall be presided over by the Chief Executive Officer of the corporation or the Chair of the Board, if any, or in their absence, by the Vice Chair of the Board, if any, or in the Vice Chair's absence, by the President of the corporation (if different than the Chief Executive Officer), or in the President's absence, by a Vice President of the corporation, or in the absence of all of the foregoing persons, by a chair designated by the Board of Directors.

(b) The Board of Directors may adopt by resolution such rules, regulations and procedures for the conduct of any meeting of stockholders of the corporation as it shall deem appropriate, including, without limitation, such guidelines and procedures as it may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chair of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chair, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chair of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders of record of the corporation, their duly authorized and constituted proxies or such other persons as shall be determined; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants.

(c) The chair of the meeting shall announce at the meeting when the polls for each matter to be voted upon at the meeting will be opened and closed. After the polls close, no ballots, proxies or votes or any revocations or changes thereto may be accepted.

(d) In advance of any meeting of stockholders of the corporation, the Board of Directors, the Chair of the Board, the Chief Executive Officer or the President shall appoint one or more inspectors of election to act at the meeting and make a written report thereof. One or more other

persons may be designated as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is present, ready and willing to act at a meeting of stockholders of the corporation, the chair of the meeting shall appoint one or more inspectors to act at the meeting. Unless otherwise required by law, inspectors may be officers, employees or agents of the corporation. Each inspector, before entering upon the discharge of such inspector's duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability. The inspector shall have the duties prescribed by law and shall take charge of the polls and, when the vote is completed, shall make a certificate of the result of the vote taken and of such other facts as may be required by law. Every vote taken by ballots shall be counted by a duly appointed inspector or duly appointed inspectors.

1.13 No Action by Consent in Lieu of a Meeting. Stockholders of the corporation may not take any action by written consent in lieu of a meeting.

ARTICLE II
DIRECTORS

1.1 General Powers. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by law or the Certificate of Incorporation.

1.2 Number, Election and Qualification. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the corporation shall be established by the Board of Directors. The election of directors need not be by written ballot. Directors need not be stockholders of the corporation.

1.3 Chair of the Board; Vice Chair of the Board. The Board of Directors may appoint from its members a Chair of the Board and a Vice Chair of the Board, neither of whom need be an employee or officer of the corporation. If the Board of Directors appoints a Chair of the Board, such Chair shall perform such duties and possess such powers as are assigned by the Board of Directors and, if the Chair of the Board is also designated as the corporation's Chief Executive Officer, shall have the powers and duties of the Chief Executive Officer prescribed in Section 3.7 of these By-laws. If the Board of Directors appoints a Vice Chair of the Board, such Vice Chair shall perform such duties and possess such powers as are assigned by the Board of Directors. Unless otherwise provided by the Board of Directors, the Chair of the Board or, in the Chair's absence, the Vice Chair of the Board, if any, shall preside at all meetings of the Board of Directors.

1.4 Classes of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes: Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The allocation of directors among classes shall be determined by resolution of the Board of Directors.

1.5 Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

1.6 Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board of Directors pursuant to Section 2.2 of these By-laws shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

1.7 Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors, unless a greater number is required by law or by the Certificate of Incorporation.

1.8 Removal. Subject to the rights of holders of any series of Preferred Stock, directors of the corporation may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.

1.9 Vacancies. Subject to the rights of holders of any series of Preferred Stock, any vacancy or newly-created directorship on the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and shall not be filled by the stockholders. A director elected to fill a vacancy shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor or until such director's earlier death, resignation or removal.

1.10 Resignation. Any director may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal office or to the Chair of the Board, the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event.

1.11 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders of the corporation.

1.12 Special Meetings. Special meetings of the Board of Directors may be held at any time and place designated in a call by the Chair of the Board, the Chief Executive Officer, the President, two or more directors, or by one director in the event that there is only a single director in office.

1.13 Notice of Special Meetings. Notice of the date, place and time of any special meeting of directors shall be given to each director by the Secretary of the corporation or by the officer or one of the directors calling the meeting. Notice shall be duly given to each director (a) in person or by telephone at least 24 hours in advance of the meeting, (b) by sending written notice by reputable overnight courier, telecopy, facsimile or electronic transmission, or delivering written notice by hand, to such director's last known business, home or electronic transmission address at least 48 hours in advance of the meeting, or (c) by sending written notice by first-class mail to such director's last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

1.14 Meetings by Conference Communications Equipment. Directors may participate in meetings of the Board of Directors or any committee thereof by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.

1.15 Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent to the action in writing or by electronic transmission. After an action is taken, the consent or consents relating thereto shall be filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

1.16 Committees. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation with such lawfully delegable powers and duties as the Board of Directors thereby confers, to serve at the pleasure of the Board of Directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers which may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these By-laws for the Board of Directors. Except as otherwise provided in the Certificate of Incorporation, these By-laws, or the resolution of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

1.17 Compensation of Directors. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary entities in any other capacity and receiving compensation for such service.

ARTICLE III
OFFICERS

1.1 Titles. The officers of the corporation shall consist of a Chief Executive Officer, a President, and a Secretary, and such other officers with such other titles as the Board of Directors shall determine, including a Chief Financial Officer, a Treasurer, and one or more Vice Presidents, Assistant Treasurers and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate to carry on the business of the corporation.

1.2 Election. Each officer of the corporation shall be elected by the Board of Directors and shall hold office for such term as may be prescribed by the Board of Directors and until such person's successor shall have been duly elected and qualified, or until such person's earlier death, disqualification, resignation or removal.

1.3 Qualification. No officer need be a stockholder or director of the corporation. Any two or more offices may be held by the same person.

1.4 Tenure. Except as otherwise provided by law, by the Certificate of Incorporation or by these By-laws, each officer shall hold office until such officer's successor is elected and qualified, unless a different term is specified in the resolution electing or appointing such officer, or until such officer's earlier death, resignation or removal.

1.5 Resignation and Removal. Any officer may resign by delivering a written resignation to the corporation at its principal office or to the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event. Any officer may be removed at any time, with or without cause, by vote of a majority of the directors then in office. Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following such officer's resignation or removal, or any right to damages on account of such removal, whether such officer's compensation be by the month or by the year or otherwise, unless such compensation is expressly provided for in a duly authorized written agreement with the corporation.

1.6 Vacancies. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices other than those of Chief Executive Officer, President, and Secretary. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is elected and qualified, or until such officer's earlier death, resignation or removal.

1.7 President; Chief Executive Officer. Unless the Board of Directors has designated another person as the corporation's Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The Chief Executive Officer shall have general charge and supervision of the business of the corporation subject to the direction of the Board of Directors, and shall perform all duties and have all powers that are commonly incident to the office of chief executive or that are delegated to such officer by the Board of Directors. The President shall perform such other duties and shall have such other powers as the Board of Directors or the Chief Executive Officer (if the President is not the Chief Executive Officer) may from time to time prescribe. In the event of the absence, inability or refusal to act of the Chief Executive Officer or the President (if the President is not the Chief Executive Officer), the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the Chief Executive Officer and when so performing such duties shall have all the powers of and be subject to all the restrictions upon the Chief Executive Officer.

1.8 Chief Financial Officer. The Chief Financial Officer shall exercise all the powers and perform the duties of the office of the chief financial officer and in general have overall supervision of the financial operations of the corporation. The Chief Financial Officer shall, when requested, counsel with and advise the other officers of the corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time prescribe.

1.9 Vice Presidents. Each Vice President shall perform such duties and possess such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. The

Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

1.10 Secretary and Assistant Secretaries.

(a) The Secretary shall perform such duties and shall have such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings (or designate any other person to serve as secretary of the meeting to keep a record of the proceedings), to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

(b) Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

(c) In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the chair of the meeting shall designate a secretary for the meeting to keep a record of the proceedings of the meeting.

1.11 Treasurer and Assistant Treasurers.

(a) The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned by the Board of Directors or the Chief Executive Officer. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these By-laws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

(b) The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

1.12 Salaries. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.

1.13 Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof. To the extent not set forth in these By-laws, the officers of the corporation shall have such authority and perform such duties as shall be prescribed by the Board of Directors or by officers authorized by the Board of Directors to prescribe their duties. To the extent that such duties are not so prescribed, such officers shall have such authority and perform the duties which generally pertain to their respective offices, subject to the control of the Chief Executive Officer or the Board of Directors.

ARTICLE IV
CAPITAL STOCK

1.1 Issuance of Stock. Subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation or the whole or any part of any shares of the authorized capital stock of the corporation held in the corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such lawful consideration and on such terms as the Board of Directors may determine.

1.2 Stock Certificates; Uncertificated Shares.

(a) The shares of the corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of the corporation's stock shall be uncertificated shares. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number of shares held by such holder registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the DGCL.

(b) Each certificate for shares of stock which are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these By-laws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

(c) If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

(d) Within a reasonable time after the issuance or transfer of uncertificated shares, the corporation shall send to the registered owner thereof a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to Sections 151, 202(a) or 218(a) of the DGCL or, with respect to Section 151 of DGCL, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

1.3 Transfers. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these By-laws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these By-laws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these By-laws.

1.4 Lost, Stolen or Destroyed Certificates. The corporation may issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen or destroyed, upon

such terms and conditions as the Board of Directors may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond as the Board of Directors may require for the protection of the corporation or any transfer agent or registrar.

1.5 Record Date.

(a) The Board of Directors may fix in advance a date as a record date for the determination of the stockholders entitled to notice of or to vote at any meeting of stockholders, or entitled to receive payment of any dividend or other distribution or allotment of any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action. Such record date shall not precede the date on which the resolution fixing the record date is adopted, and such record date shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action to which such record date relates.

(b) If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. If no record date is fixed, the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

(c) A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

1.6 Regulations. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

ARTICLE V
GENERAL PROVISIONS

1.1 Fiscal Year. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of January of each year and end on the last day of December in each year.

1.2 Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.

1.3 Waiver of Notice. Whenever notice is required to be given by law, by the Certificate of Incorporation, by these By-laws, or in accordance with the provisions of the DGCL, a written waiver signed by the person entitled to such notice, or a waiver by electronic transmission by the person entitled to such notice, whether before, at or after the time of the event for which notice is to be given, shall be deemed equivalent to the giving of such notice. Neither the business nor the purpose of any meeting need be specified in any such waiver. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

1.4 Voting of Securities. Except as the Board of Directors may otherwise designate, the Chief Executive Officer, the President or the Treasurer may waive notice of, vote, or appoint any person or persons to vote, on behalf of the corporation at, and act as, or appoint any person or persons to act as, proxy or attorney-in-fact for this corporation (with or without power of substitution) at, any meeting of stockholders or securityholders of any other entity, the securities of which may be held by this corporation.

1.5 Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.

1.6 Certificate of Incorporation. All references in these By-laws to the Certificate of Incorporation shall be deemed to refer to the certificate of incorporation of the corporation, as amended and in effect from time to time.

1.7 Severability. Any determination that any provision of these By-laws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these By-laws.

1.8 Pronouns. All pronouns used in these By-laws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

1.9 Forum Selection By-law.

(a) Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of the corporation; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of the corporation, to the corporation or the corporation's stockholders; (iii) any action or proceeding asserting a claim against the corporation or any current or former director, officer or other employee of the corporation, arising out of or pursuant to any provision of the DGCL, the Certificate of Incorporation or these By-laws (as each may be amended from time to time); (iv) any action or proceeding to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or these By-laws (including any right, obligation, or remedy thereunder); (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against the corporation or any director, officer or other employee of the corporation, governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. This Section 5.9(a) shall not apply to suits brought to enforce a duty or

liability created by the Securities Act of 1933, as amended (the “Securities Act”), the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

(b) Unless the corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

(c) If any action the subject matter of which is within the scope of subparagraph (a) of this Section 5.9 is filed in a court other than a court located within the State of Delaware (a “Foreign Action”) in the name of any stockholder, such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce subparagraph (a) of this Section 5.9 (an “Enforcement Action”) and (ii) having service of process made upon such stockholder in any such Enforcement Action by service upon such stockholder’s counsel in the Foreign Action as agent for such stockholder.

(d) If any provision of this Section 5.9 shall be held to be invalid, illegal or unenforceable as applied to any person, entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Section 5.9, and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

(e) For the avoidance of doubt, any person or entity purchasing or otherwise acquiring or holding any interest in any security of the corporation shall be deemed to have notice of and consented to the provisions of this Section 5.9.

ARTICLE VI
AMENDMENTS

These By-laws may be altered, amended or repealed, in whole or in part, or new By-laws may be adopted by the Board of Directors or by the stockholders as provided in the Certificate of Incorporation.

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: August 10, 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: August 10, 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 June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: August 10, 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 June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: August 10, 2023

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