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

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36395

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

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

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

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

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

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

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

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

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

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

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

As of November 9, 2022, 84,825,481 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, submit and obtain United States Food and Drug Administration, or FDA, or foreign regulatory authority approval and commercialize our product candidates, if approved, 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;*
- *The terms and conditions of our strategic collaborations, including our out-license agreements for commercialization of XACIATO and Ovaprene®;*
- *A decision by the collaborators with whom we have entered into out-license agreements for commercialization of XACIATO and Ovaprene to discontinue their interest in XACIATO and Ovaprene, respectively, or to terminate such agreement, or the failure of our out-license agreement for Ovaprene to become fully effective;*
- *The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;*
- *Difficulties with establishing and maintaining collaborations relating to the development and/or commercialization, if approved, of our product candidates on a timely basis or on acceptable terms, or at all;*
- *Our loss of, or inability to attract, key personnel;*
- *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;*
- *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;*

- *Adverse 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 it does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that it interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *Failure to monetize our portfolio through licenses, partnerships or other types of commercialization agreements, structured financings, or on our own;*
- *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 less competitive or obsolete;*
- *The impact of the macroeconomic conditions, geopolitical events, the COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat or natural disasters on our business, operations and financial condition, or on those of third parties on which we rely;*
- *Reduced interest in women's health relative to other healthcare sectors by the investment community or pharmaceutical companies and other potential development and commercialization collaborators;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems and data 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 those product candidates to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in pre-clinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *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 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 unexpected safety concerns related to our product or product candidates, or third-party products or product candidates that share similar characteristics or drug substances;*
- *Product liability claims or governmental investigations;*
- *Strict government regulations on our business, including laws and regulations designed to control health care product pricing and various fraud and abuse laws, including, without limitation, the Inflation Reduction Act of 2022, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act;*

- *Regulations governing the production or marketing of XACIATO and any future products; and*
- *Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.*

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

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

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	September 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 40,389,546	$ 51,674,087
Other receivables	2,292,041	1,145,317
Prepaid expenses	6,885,498	2,476,612
Total current assets	49,567,085	55,296,016
Property and equipment, net	72,833	26,041
Other non-current assets	736,514	485,120
Total assets	$ 50,376,432	$ 55,807,177
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,477,192	$ 2,103,083
Accrued expenses	4,136,330	3,136,244
Deferred grant funding	14,836,416	10,542,983
Current portion of lease liabilities	388,135	270,546
Total current liabilities	22,838,073	16,052,856
Deferred license revenue	1,000,000	1,000,000
Lease liabilities long-term	194,587	—
Total liabilities	24,032,660	17,052,856
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.01 par value, 5,000,000 shares authorized; None issued and outstanding	—	—
Common stock, $0.0001 par value; 240,000,000 shares authorized; 84,825,481 and 83,944,119 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	8,482	8,394
Accumulated other comprehensive loss	(530,740)	(154,973)
Additional paid-in capital	151,997,447	149,027,802
Accumulated deficit	(125,131,417)	(110,126,902)
Total stockholders' equity	26,343,772	38,754,321
Total liabilities and stockholders' equity	$ 50,376,432	$ 55,807,177

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue				
License fee revenue	$ —	$ —	$ 10,000,000	$ —
Total revenue	—	—	10,000,000	—
Operating expenses				
General and administrative	2,651,543	2,211,334	8,014,424	5,949,299
Research and development	4,462,250	10,432,603	17,065,497	23,501,098
License fee expense	25,000	25,000	75,000	75,000
Total operating expenses	7,138,793	12,668,937	25,154,921	29,525,397
Loss from operations	(7,138,793)	(12,668,937)	(15,154,921)	(29,525,397)
Other income	118,950	1,508	150,406	1,686
Gain on extinguishment of note payable	—	—	—	369,887
Net loss	$ (7,019,843)	$ (12,667,429)	$ (15,004,515)	$ (29,153,824)
Foreign currency translation adjustments	(230,748)	(63,281)	(375,767)	(79,002)
Comprehensive loss	$ (7,250,591)	$ (12,730,710)	$ (15,380,282)	$ (29,232,826)
Loss per common share - basic and diluted	$ (0.08)	$ (0.18)	$ (0.18)	$ (0.45)
Weighted average number of shares outstanding:				
Basic and diluted	84,822,516	70,775,508	85,553,134	64,196,162

See accompanying notes.

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

Nine Months Ended September 30, 2022

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

See accompanying notes.

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

Nine Months Ended September 30, 2021

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount				
Balance at December 31, 2020	**41,596,253**	**$ 4,159**	**$ 70,366,293**	**$ (91,388)**	**$ (71,430,797)**	**$ (1,151,733)**
Stock-based compensation	—	—	365,911	—	—	365,911
Issuance of common stock, net of issuance costs	5,664,069	567	11,323,573	—	—	11,324,140
Issuance of common stock from the exercise of warrants	52,500	5	50,395	—	—	50,400
Net loss	—	—	—	—	(7,323,644)	(7,323,644)
Foreign currency translation adjustments	—	—	—	(6,841)	—	(6,841)
Balance at March 31, 2021	**47,312,822**	**$ 4,731**	**$ 82,106,172**	**$ (98,229)**	**$ (78,754,441)**	**$ 3,258,233**
Stock-based compensation	—	$ —	$ 405,478	$ —	$ —	$ 405,478
Issuance of common stock, net of issuance costs	10,096,701	1,010	13,250,914	—	—	13,251,924
Net loss	—	—	—	—	(9,162,751)	(9,162,751)
Foreign currency translation adjustments	—	—	—	(8,880)	—	(8,880)
Balance at June 30, 2021	**57,409,523**	**$ 5,741**	**$ 95,762,564**	**$ (107,109)**	**$ (87,917,192)**	**$ 7,744,004**
Stock-based compensation	—	—	439,497	—	—	439,497
Issuance of common stock, net of issuance costs	18,282,392	1,828	35,010,220	—	—	35,012,048
Issuance of common stock from the exercise of warrants	212,985	21	204,445	—	—	204,466
Issuance of common stock in connection with milestone payment	696,724	70	1,219,216	—	—	1,219,286
Net loss	—	—	—	—	(12,667,429)	(12,667,429)
Foreign currency translation adjustments	—	—	—	(63,281)	—	(63,281)
Balance at September 30, 2021	**76,601,624**	**$ 7,660**	**$ 132,635,942**	**$ (170,390)**	**$(100,584,621)**	**$ 31,888,591**

See accompanying notes.

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

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (15,004,515)	$ (29,153,824)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	13,580	19,366
Stock-based compensation	1,626,378	1,210,886
Non-cash operating lease cost	29,320	(69,356)
Gain on early termination of lease	(46,477)	—
Non-cash loss on settlement of contingent liability	—	44,286
Gain on extinguishment of notes payable and accrued interest	—	(369,887)
Changes in operating assets and liabilities:		
Other receivables	(1,146,724)	303,921
Prepaid expenses	(4,408,886)	(661,849)
Other non-current assets	77,939	57,247
Accounts payable	1,374,109	(415,602)
Accrued expenses	1,000,086	594,629
Deferred grant funding	4,293,433	9,592,045
Net cash used in operating activities	(12,191,757)	(18,848,138)
Cash flows from investing activities		
Purchases of property and equipment	(60,372)	(14,524)
Net cash used in investing activities	(60,372)	(14,524)
Cash flows from financing activities		
Net proceeds from issuance of common stock	1,218,750	59,588,112
Proceeds from the exercise of stock options	124,605	254,866
Net cash provided by financing activities	1,343,355	59,842,978
Effect of exchange rate changes on cash and cash equivalents	(375,767)	(79,002)
Net change in cash and cash equivalents	(11,284,541)	40,901,314
Cash and cash equivalents, beginning of period	51,674,087	4,669,467
Cash and cash equivalents, end of period	$ 40,389,546	$ 45,570,781
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities, net	$ 585,942	$ 308,533
Forgiveness of Paycheck Protection Program note payable	$ —	$ 369,887
Settlement of contingent closing consideration liability with stock issuance in connection with acquisition of business	$ —	$ 925,000
Milestone payment paid in common stock	$ —	$ 250,000

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, fertility, and vaginal and sexual health, 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 FDA-approved 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 a license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO. That agreement became effective on June 30, 2022, and in July 2022, the Company received the upfront $10.0 million non-refundable and non-creditable payment due under the agreement.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited 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, 2021, or the 2021 10-K.

Going Concern

The Company prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. Although the Company reported net income of approximately $0.4 million for its fiscal quarter ended June 30, 2022 as a result of the upfront one-time payment due under its license agreement with Organon to commercialize XACIATO, 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 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

As of September 30, 2022, the Company had an accumulated deficit of approximately $125.1 million, cash and cash equivalents of approximately $40.4 million, a deferred grant funding liability of $14.8 million (representing grant funds received that may be applied solely for the development of DARE-LARC1 and which are included in cash and cash equivalents), and working capital of approximately $26.7 million. For the nine months ended September 30, 2022, the Company incurred a net loss of approximately $15.0 million and had negative cash flow from operations of approximately $12.2 million.

The Company expects its primary uses of capital to be staff-related expenses, the cost of clinical trials and regulatory activities related to its product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments due to third-parties under the Company's in-license and acquisition agreements including upon the occurrence of commercial milestones for XACIATO and development milestones for the Company’s product candidates, legal expenses, other regulatory expenses and general overhead costs. The Company’s future funding requirements could also include significant costs related to commercialization of its product candidates, if approved, depending on the type, nature and terms of commercial collaborations the Company establishes.

The Company has devoted significant resources to building its portfolio of product candidates and to research and development activities related to these product candidates. The Company or its licensees must obtain regulatory approvals to market and sell any of its product candidates in the future and to market and sell XACIATO anywhere outside the U.S. The Company will need to generate sufficient safety and efficacy data on each of its product candidates in order to apply for regulatory approvals and for such assets to be attractive assets to potential strategic collaborators to license or to acquire, and for the Company to generate revenue through license fees, royalties on net revenues and commercial milestones related to such product candidates.

Based on the Company's current operating plan estimates, the Company does not have sufficient cash to satisfy its working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying financial statements. The Company will need to raise substantial additional capital to continue to fund its operations and to execute its current strategy. The Company may continue to seek to raise capital through the sale of shares of its common stock under its at-the-market, or ATM, sales agreement or through other types of equity transactions. However, when the Company can effect such sales and the amount of shares the Company can sell depends on a variety of factors including, among others, market conditions, the trading price of its common stock, its determination as to the appropriate sources of funding for its operations, and the number of authorized shares of common stock that are available for issuance. For the foreseeable future, the Company will evaluate and may pursue a variety of capital raising options on an on-going basis, including equity and debt financings, government or other grant funding, collaborations, structured financings, and strategic alliances, or other similar types of arrangements, to cover its operating expenses, and the cost of any license or other acquisition of new product candidates or technologies. The amount and timing of the Company's capital needs have been, and will continue to be, highly dependent on many factors, including the product development programs the Company chooses to pursue, the pace and results of its clinical development efforts, and the nature and extent of the potential expansion of its product candidate portfolio, if any. If the Company raises capital through collaborations, structured financings, strategic alliances or other similar types of arrangements, it may be required to relinquish some or all of its rights to potential revenue or to intellectual property rights for its product candidates on terms that are not favorable to the Company.

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. In addition, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders, and debt financings may subject the Company to restrictive covenants, operational restrictions and security interests in its assets. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will not be able to continue development of its product candidates, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If the Company becomes unable to continue as a going concern, the Company may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its 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 2021 10-K. Since the date of those consolidated financial statements, there have been no material changes to the Company’s significant accounting policies.

Fair Value of Financial Instruments

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

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

The following tables present the classification within the fair value hierarchy of financial assets and liabilities that are remeasured on a recurring basis as of September 30, 2022 and December 31, 2021. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) or using unobservable inputs (Level 3) as of September 30, 2022 or December 31, 2021.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at September 30, 2022				
Current assets:				
Cash equivalents [1]	$ 39,083,471	$ —	$ —	$ 39,083,471
Balance at December 31, 2021				
Current assets:				
Cash equivalents [1]	$ 49,666,064	$ —	$ —	$ 49,666,064

[1] Represents cash held in money market funds.

Revenue Recognition

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

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

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

License Fees. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses 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). To date, 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. To date, 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. To date, the Company has not recognized any milestone revenue.

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 pursuant to which Organon will obtain 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. The agreement became effective on June 30, 2022 following the satisfaction of closing conditions.

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

Upfront Payment. Upon the effectiveness of the agreement, the Company recorded the transaction price of $10.0 million as license fee revenue in the accompanying condensed consolidated statement of operations. The $10.0 million was received in July 2022.

Royalty and Milestone Payments. The Company will be entitled to receive tiered double-digit royalties based on net sales and up to $182.5 million in milestone payments as follows: $2.5 million following the first commercial sale of a licensed product in the United States; and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets.

The royalty period for each licensed product will continue on a country-by-country basis from the first commercial sale of the licensed product in the country until the expiration of the later of (i) the date that no valid patent claim would be infringed in the absence of the license granted under the agreement by the sale of the licensed product in the country, (ii) 10 years after the end of the month in which the first commercial sale of the licensed product in the country occurred, and (iii) the expiration of regulatory market exclusivity for the licensed product in that country.

The Company concluded at the inception of the agreement that the transaction price 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 three and nine months ended September 30, 2022, 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).

Regulatory Interactions and Product Supply. The Company will be 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.

Term. 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.

Other. The terms of the agreement provide Organon exclusive worldwide rights of first negotiation for specified potential future products of the Company.

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. 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 Clinical Trial and Manufacturing Activities Fee. Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with 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 (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 September 30, 2022, neither of the foregoing had occurred. The $1.0 million payment is recorded as long-term deferred license revenue in the Company's condensed consolidated balance sheet at September 30, 2022 and December 31, 2021.

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

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

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

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

Strategic Agreements for Pipeline Development

Hammock/MilanaPharm Assignment and License Agreement

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

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

License Fees. A total of $235,000 in license fees were payable to MilanaPharm, the final installment of which was $110,000 paid in 2020.

Milestone Payments. The Company paid MilanaPharm $300,000 in the aggregate upon achievement of certain clinical and regulatory development milestones, $50,000 of which was paid in 2020 and $250,000 of which was paid 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 use and urological use, and up to $250,000 upon the first commercial sale in the United States of successive licensed products for vaginal or urological use. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products, the Company must pay $1.0 million to MilanaPharm.

Foreign Sublicense Income. The Company will pay MilanaPharm a low double-digit percentage of all income received by the Company or its affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions.

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

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

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

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

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

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

Fees. A total of $512,500 in fees were payable to Hammock, the final installment of which was $137,500 paid in 2020.

Milestone Payments. The Company will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $100,000 of which was paid in 2020 and $750,000 of which was paid in 2021. The remaining milestone does not relate to a bacterial vaginosis product.

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

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene and must meet certain minimum spending amounts per year, including $2.5 million per year to cover such activities until a final premarket approval application, or PMA, is filed, or until the first commercial sale of Ovaprene, whichever occurs first. ADVA-Tec will conduct certain research and development work as necessary to allow the Company to seek a PMA from the FDA and will provide the Company with clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, on commercially reasonable terms.

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

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

Milestone Payments. The Company will pay to ADVA-Tec: (1) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones, $200,000 of which was paid in 2021; and (2) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones. The remaining development and regulatory milestones include: the FDA's approval to commence a pivotal clinical trial; successful completion of such pivotal clinical trial; the FDA's acceptance of a PMA filing for Ovaprene; the FDA's approval of the PMA for Ovaprene; CE Marking of Ovaprene in at least three designated European countries; obtaining regulatory approval in at least three designated European countries; and obtaining regulatory approval in Japan. If the Company sublicenses its rights to Ovaprene, the Company will pay to ADVA-Tec a single digit percentage of the upfront payment or license fee due on or around the effective date of the sublicense.

Royalty Payments. The Company will pay to ADVA-Tec tiered royalties of between 1% and 10% based on percentages of annual net sales of Ovaprene by the Company in specified regions. If the Company sublicenses its rights to Ovaprene, in lieu of the foregoing royalties, the Company will pay to ADVA-Tec a low mid-double digit percentage of the royalty revenue the Company receives from the sublicensee.

Term. Unless earlier terminated, the license the Company received under the agreement continues on a country-by-country basis until the later of the life of the licensed patents or the Company's last commercial sale of Ovaprene. In addition to customary termination rights for both parties: (A) the Company may terminate the agreement with or without cause in whole or on a country-by-country basis upon 60 days prior written notice; and (B) ADVA-Tec may terminate the agreement if the Company develops or commercializes any non-hormonal ring-based vaginal contraceptive device competitive to Ovaprene or if the Company fails to: (1) in certain limited circumstances, commercialize Ovaprene in certain designated countries within three years of the first commercial sale of Ovaprene; (2) satisfy the annual spending obligation described above, (3) use commercially reasonable efforts to complete all necessary pre-clinical and clinical studies required to support and submit a PMA, (4) conduct clinical trials as set forth in the development plan to which the Company and ADVA-Tec agree, and as may be modified by a joint research committee, unless such failure is caused by events outside of the Company's reasonable control, or (5) enroll a patient in the first non-significant risk medical device study or clinical trial as allowed by an institutional review board within six months of the production and release of Ovaprene, unless such failure is caused by events outside of the Company's reasonable control.

SST License and Collaboration Agreement

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

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

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

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

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

Royalty Payments. SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products by the Company in the single digits to the low double digits. If the Company sublicenses Licensed Products, SST will be eligible to receive the greater of a low mid-double digit percentage of the sublicense revenue the Company receives from the sublicensee or tiered royalties based on percentages of annual net sales of Licensed Products by the sublicensee in the single digits. In each case, the royalties are subject to customary reductions and offsets.

Milestone Payments. SST will be eligible to receive payments (1) ranging from $0.5 million to $18.0 million in the aggregate on achieving certain clinical and regulatory milestones in the U.S. and worldwide, and (2) between $10.0 million to $100.0 million in the aggregate upon achieving certain commercial sales milestones. If the Company has entered into strategic development or distribution partnerships related to the Licensed Products at the time certain milestones are achieved, additional milestone payments (1) ranging from $2.0 million to $10.0 million upon achieving certain clinical and regulatory milestones, and (2) ranging from $10.0 million to $125.0 million upon achieving certain commercial sales milestones would be due to SST.

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

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

Catalent JNP License Agreement

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

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

Annual Maintenance Fee. The Company will pay an annual license maintenance fee to Catalent on each anniversary of the date of the agreement, the amount of which will be $50,000 for the first two years and $100,000 thereafter, and which will be creditable against royalties and other payments due to Catalent in the same calendar year but may not be carried forward to any other year. The Company made the first payments in April 2019.

Milestone Payments. The Company must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, $1.0 million of which became payable in the third quarter of 2021, and in accordance with the license agreement, the amount payable was offset by the $100,000 annual maintenance fee, resulting in a net amount of $900,000 paid during the third quarter of 2021, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the agreement.

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

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

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

Adare Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharma Solutions (formerly known as Adare Pharmaceuticals and Orbis Biosciences, and which the Company refers to as Adare), for the development of two long-acting injectable etonogestrel contraceptives with 6- and 12-month durations (now referred to as ADARE-204 and ADARE-214, respectively). The agreement provides the Company with an option to negotiate an exclusive license agreement for the programs if the Company funds the conduct of specified development work by Adare.

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.

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

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

Royalty Payments. The Company will pay Hennepin low-single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement.

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

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

MBI Acquisition

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

In connection with the MBI acquisition, the Company issued an aggregate of approximately 3.0 million shares of its common stock to the holders of shares of MBI's capital stock outstanding immediately prior to the effective time of the merger and agreed to pay the 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 acquired by the Company in the merger; (c) tiered royalty payments ranging from low single-digit to low double-digit percentages of the proceeds from annual net sales of such products received by the Company (but not by sublicensees), subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. The Company agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to DARE-LARC1. In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events, $1.0 million of which was recorded as contingent consideration on the Company's consolidated balance sheets upon the completion of the MBI acquisition and $250,000 of which was expensed in 2021. In July 2021, the Company's board of directors elected to make these milestone payments in shares of the Company's common stock, to the extent permissible under the terms of the merger agreement with MBI, 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 accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021. See Note 7.

Pear Tree Acquisition

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

Milestone Payments. The Company must make contingent payments to certain Pear Tree licensors and former stockholders of Pear Tree that become payable upon achievement of specified clinical, regulatory and commercial milestones, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock.

Royalty Payments. Subject to royalty reductions and offsets, the former stockholders of Pear Tree and certain Pear Tree licensors will be eligible to receive tiered royalties based on percentages of net sales of certain products by the Company and a percentage of royalties the Company receives based on net sales of certain products by sublicensees.

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.

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 "at-the-market," or ATM, equity offering program under which SVB Leerink acts 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, 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) and the base prospectus included therein, originally filed with the SEC on March 30, 2021, and declared effective on April 7, 2021, and the prospectus supplement dated October 13, 2021 relating to the offering of up to $50.0 million in shares of the Company's common stock under this sales agreement, and any subsequent prospectus supplement filed with the SEC related to this ATM equity offering program.

During the nine months ended September 30, 2022, the Company sold approximately 751,000 shares of common stock under this agreement for gross proceeds of approximately $1.3 million and incurred offering expenses of approximately $42,000.

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 acts as the Company's agent. Under the sales agreement, the Company may issue and sell up to $50.0 million of shares of its common stock. The Company agreed to pay a commission equal to 3% of the gross proceeds of any common stock sold under the agreement, plus certain legal expenses. Any 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) and the base prospectus included therein, originally filed with the SEC on March 30, 2021, and declared effective on April 7, 2021, and the prospectus supplement dated April 7, 2021 filed with the SEC on April 8, 2021.

During the nine months ended September 30, 2022, the Company sold no shares under this agreement. During the nine months ended September 30, 2021, the Company sold approximately 26.0 million shares of common stock under this agreement for gross proceeds of approximately $46.9 million and incurred offering expenses of approximately $1.6 million.

2018 ATM Sales Agreement

In January 2018 the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC, or Wainwright, relating to the offering and sale of shares of its common stock from time to time in an ATM equity offering program through Wainwright, acting as sales agent. Under the agreement, Wainwright was entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold under the agreement. In March 2021, the Company provided notice to Wainwright to terminate the agreement, and the agreement terminated in April 2021. During the nine months ended September 30, 2021, the Company sold approximately 3.3 million shares of common stock under this agreement for gross proceeds of approximately $7.7 million and incurred offering expenses of approximately $245,000.

Equity Line

In April 2020, the Company entered into a purchase agreement, or the Purchase Agreement, and a registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the Purchase Agreement, the Company had the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park was obligated to purchase up to $15.0 million of the Company's common stock. The Company incurred legal, accounting, and other fees related to the Purchase Agreement of approximately $374,000. These costs were amortized and expensed as shares were sold under the Purchase Agreement. As of December 31, 2021, the Company had sold and Lincoln Park had purchased $15.0 million of the Company's common stock under the Purchase Agreement, there were no unamortized costs, and no more shares of common stock may be sold by the Company to Lincoln Park under the Purchase Agreement. During the nine months ended September 30, 2021, the Company sold, and Lincoln Park purchased, 4.8 million shares under the Purchase Agreement for gross proceeds to the Company of approximately $7.0 million and recognized offering expenses of approximately $207,000.

Common Stock Warrants

In February 2018, the Company closed an underwritten public offering in connection with which the Company issued to the investors in that offering warrants exercisable through February 2023 and that initially had an exercise price of $3.00 per share. The warrants include a price-based anti-dilution provision, which provides that, subject to certain limited exceptions, the exercise price of the warrants will be reduced each time the Company issues or sells (or is deemed to issue or sell) securities for a net consideration per share less than the exercise price of those warrants in effect immediately prior to such issuance or sale. In addition, subject to certain exceptions, if the Company issues, sells or enters into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of the Company's common stock, the warrant holders have the right to substitute such variable price for the exercise price of the warrant then in effect. These warrants are exercisable only for cash, unless a registration statement covering the shares issued upon exercise of the warrants is not effective, in which case the warrants may be exercised on a cashless basis. A registration statement covering the shares issued upon exercise of the warrants is currently effective. The Company estimated the fair value of the warrants as of February 15, 2018 to be approximately $3.0 million which was recorded in equity as of the grant date. The Company early adopted ASU 2017-11 as of January 1, 2018 and recorded the fair value of the warrants as equity.

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

During the nine months ended September 30, 2022, no warrants were exercised. During the nine months ended September 30, 2021, warrants to purchase 265,485 shares of common stock were exercised for gross proceeds of $254,866. As of September 30, 2022, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants	Exercise Price		Expiration Date
6,500	$	10.00	04/04/2026
1,374,515	$	0.96	02/15/2023
1,381,015			

5. STOCK-BASED COMPENSATION

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan, or the ESPP, became effective in April 2014, but no offering period has been initiated thereunder since January 2017. There was no stock-based compensation related to the ESPP for the nine months ended September 30, 2022 or September 30, 2021.

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. On June 23, 2022, the Amended 2014 Plan was superseded by the 2022 Plan (as defined below), and no further awards will be granted under the Amended 2014 Plan. Awards outstanding under the Amended 2014 Plan will continue to remain outstanding pursuant to their terms and conditions.

2022 Stock Incentive Plan

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

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

Summary of Stock Option Activity

The table below summarizes stock option activity under the Company's stock incentive plans and related information for the nine months ended September 30, 2022. The exercise price of all options granted during the nine months ended September 30, 2022 was equal to the market value of the Company's common stock on the date of grant. As of September 30, 2022, unamortized stock-based compensation expense of approximately $4.7 million will be amortized over a weighted average period of 2.56 years. At September 30, 2022, 9,576,581 shares of common stock were available for future awards granted under the 2022 Plan.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2021	4,717,602	$ 1.65
Granted	2,346,692	1.50
Exercised	(130,322)	0.96
Canceled/forfeited	(321,418)	1.94
Expired	—	—
Outstanding at September 30, 2022	6,612,554	$ 1.60
Exercisable at September 30, 2022	3,337,063	$ 1.49

Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 168,323	$ 144,876	$ 514,875	$ 389,913
General and administrative	$ 388,125	$ 294,621	$ 1,111,504	$ 820,973
Total	$ 556,448	$ 439,497	$ 1,626,379	$ 1,210,886

`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 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 is included as a reduction to research and development expense for the three and nine months ended September 30, 2022.

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

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

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

At September 30, 2022, the Company reported operating lease ROU assets of approximately $546,000 in other non-current assets, and approximately $388,000 and $195,000, respectively, in current portion of lease liabilities and lease liabilities long-term on the condensed consolidated balance sheet.

Total operating lease costs were approximately $116,000 and $134,000 for the three months ended September 30, 2022 and September 30, 2021, respectively, and $469,000 and $420,000 for the nine months ended September 30, 2022 and September 30, 2021, 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 $81,000 and $117,000 for the three months ended September 30, 2022 and September 30, 2021, respectively, and $231,000 and $343,000 for the nine months ended September 30, 2022 and September 30, 2021, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. At September 30, 2022, operating leases had a weighted average remaining lease term of 1.58 years.

As of September 30, 2022, future minimum lease payments under the Company's operating leases are as follows:

Remainder of 2022	$	105,000
2023		422,000
2024		93,000
Total future minimum lease payments		620,000
Less: accreted interest		37,000
Total operating lease liabilities	$	583,000

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 selected 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 to NICHD to be applied toward the costs of conducting the Ovaprene Phase 3. NICHD will be 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 paid $5.0 million of the total amount payable to NICHD, $3.5 million of which was paid during the first quarter of 2022. At September 30, 2022, the remaining amount of the Company's payment obligation under the CRADA was $0.5 million, which is due in the second quarter of 2023.

Contingent Consideration

As discussed in Note 3 above, in connection with the acquisition of MBI, the Company agreed to pay additional consideration of up to $46.5 million to the former stockholders of MBI contingent upon the achievement of specified funding, product development and regulatory milestones. In June 2021, $1.25 million of that additional consideration became payable upon the achievement of certain of the funding and product development milestone events, $1.0 million of which was previously recorded as contingent consideration on the Company's consolidated balance sheets upon the completion of the MBI acquisition and $250,000 of which was expensed in 2021. In July 2021, the Company's board of directors elected to make these milestone payments in shares of the Company's common stock, to the extent permissible under the terms of the merger agreement with MBI, and, in September 2021, the Company issued approximately 700,000 shares of its common stock to former stockholders of MBI and paid $75,000 to the stockholders' representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

Note Payable

In April 2020, due to the economic uncertainty resulting from the impact of the COVID-19 pandemic on the Company's operations and to support its ongoing operations and retain all employees, the Company applied for and received a loan of $367,285 under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, administered by the U.S. Small Business Administration, or the SBA. Under the terms of the PPP, the loan proceeds could be used for "qualifying expenses" and, subject to specified limitations in the CARES Act and under the terms of the PPP, certain amounts of the loan, including accrued interest, may be forgiven if used for qualifying expenses. In January 2021, the Company was notified that the principal balance of its PPP loan and all accrued interest, which together totaled $369,887, were fully forgiven by the SBA. The Company recorded a gain on extinguishment of note payable and debt forgiveness income with respect to such loan forgiveness in the first quarter of 2021.

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 Ovaprene, DARE-PTB1, DARE-LARC1, and ADARE-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.

Ovaprene

From 2018 through 2021, the Company received approximately $1.9 million of non-dilutive grant funding from NICHD for clinical development efforts supporting Ovaprene. All funds under the final notice of award had been disbursed as of December 31, 2021.

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 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 approximately $500 and $20,000 during the three and nine months ended September 30, 2022, respectively.

DARE-LARC1

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

The Company recorded credits to research and development expense of approximately $3,000 and $196,000 for costs related to the NICHD award during the three and nine months ended September 30, 2022, respectively. At September 30, 2022, the Company recorded a receivable of approximately $2,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

ADARE-204 and ADARE-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 ADARE-204 and ADARE-214.

The Company recorded credits to research and development expense of approximately $65,000 for costs related to the NICHD award during both the three and nine months ended September 30, 2022. At September 30, 2022, the Company recorded a receivable of approximately $65,000 for expenses incurred through such date that it believes is eligible for reimbursement under the grant.

DARE-LARC1 Non-Dilutive Grant Funding

MBI Grant Agreement

The Company's wholly-owned subsidiary, MBI, was awarded $5.4 million to support the development of DARE-LARC1 under a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation. The funding period under this agreement ended on June 30, 2021. Expenses eligible for funding were incurred, tracked and reported to the Foundation. MBI received aggregate payments under this agreement of approximately $5.4 million. At June 30, 2021, all payments under this agreement associated with research and development expenses for DARE-LARC1 had been incurred and reported to the Foundation.

2021 DARE-LARC1 Grant Agreement

In June 2021, the Company entered into an agreement with the Foundation, or the 2021 DARE-LARC1 Grant Agreement, under which the Company was awarded up to $48.95 million to support the development of DARE-LARC1. The 2021 DARE-LARC1 Grant Agreement will support technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 in non-clinical proof of principle studies. Under the 2021 DARE-LARC1 Grant Agreement, the Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Any unspent funds are recorded as a deferred grant funding liability in the Company's condensed consolidated balance sheet.

In July 2022, the Company received approximately $8.0 million from the Foundation under the 2021 DARE-LARC1 Grant Agreement. As of September 30, 2022, the Company has received a cumulative total of approximately $19.4 million in non-dilutive funding under the 2021 DARE-LARC1 Grant Agreement and recorded approximately $14.8 million of deferred grant funding liability in the Company's condensed consolidated balance sheet. Additional payments under the 2021 DARE-LARC1 Grant Agreement 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	6,612,554	4,802,666	6,612,554	4,802,666
Warrants	1,381,015	1,643,158	1,381,015	1,643,158
Total	7,993,569	6,445,824	7,993,569	6,445,824

10. SUBSEQUENT EVENTS

Ovaprene IDE Application Approval

On October 10, 2022, the FDA approved the Company's Investigational Device Exemption, or IDE, application for a single arm, open-label pivotal contraceptive efficacy study of Ovaprene and provided the Company with recommended additional study design considerations. Implementing such study design considerations will further position the study to collect safety and effectiveness data to enable the preparation of, and to support the submission of, a PMA application. The Company expects to make a $1.0 million milestone payment as a result.

Receipt of Australia Research and Development Cash Credit

On October 3, 2022, the Company received a research and development rebate from the government of Australia in the amount of approximately $786,000 for clinical work performed in Australia in 2021. The rebate is accounted for as an offset to research and development expense.

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, 2021 included in our Annual Report on Form 10-K for the year ended December 31, 2021, or our 2021 10-K, filed with the Securities and Exchange Commission, or SEC, on March 31, 2022. 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 2021 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, fertility and vaginal and sexual health. 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 exclusive global license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO. We anticipate the first commercial sale of XACIATO in the U.S. in the first half of 2023.

Our product pipeline includes diverse programs that target unmet needs in women's health in the areas of contraception, fertility and vaginal and sexual health 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 product candidates. We are also exploring opportunities to expand our portfolio by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on women's health. Our current portfolio includes two product candidates in advanced clinical development:

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

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

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring, or IVR, for the treatment of menopausal symptoms, including vasomotor symptoms, as part of hormone therapy following menopause;

- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, as an option for women with hormone-receptor positive breast cancer;
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for broader luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth.

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

- **ADARE-204 and ADARE-214**, injectable formulations of etonogestrel designed to provide contraceptive protection over 6-month and 12-month periods, respectively
- **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; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through clinical development and 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 2022, we expect to continue to focus our resources on advancement of Ovaprene and Sildenafil Cream, 3.6%, 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.

To date we have generated $10.0 million in revenue, all of which represents the upfront payment under our license agreement with Organon to commercialize XACIATO. We are subject to several risks common to biopharmaceutical companies, including dependence on key employees, dependence on third-party collaborators and service providers, competition from other companies, the need to develop commercially viable products in a timely and cost-effective manner, and the need to obtain adequate additional capital to fund the development of product candidates. We are also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of products, uncertainty of market acceptance of products, success of third parties in the marketing, sale and distribution of our products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, and product liability.

The COVID-19 pandemic remains an evolving and uncertain risk to our business, operating results, financial condition and stock price. To date, we believe the pandemic contributed to a slower than expected initial pace of enrollment in our Phase 2b clinical study of Sildenafil Cream, 3.6% and delays in commencement of clinical studies and nonclinical testing for more than one of our earlier stage clinical programs, but has not had a material adverse effect on our business as a whole. Continued uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, healthcare systems, workplace environments and capital markets, preclude any prediction as to the ultimate effect of the pandemic on our business. See the risk factor in Part I, Item 1A of our 2021 10-K titled, *The COVID-19 pandemic has negatively impacted our business and, in the future, may materially and adversely affect our business, financial condition and results and stock price, including by increasing the cost and timelines for our clinical development programs.*

XACIATO

In March 2022, we entered into an exclusive license agreement with Organon to develop, manufacture and commercialize XACIATO. The agreement became effective on June 30, 2022 following the satisfaction of closing conditions, and in July 2022, we received the $10.0 million non-refundable and non-creditable payment from Organon. We are entitled to receive a $2.5 million milestone payment following the first commercial sale of a licensed product in the United States. XACIATO launch preparation activities, including validation of the manufacturing process, are ongoing and will continue into 2023, and the first commercial sale in the U.S. is expected in the first half of 2023. We will also be eligible to receive future potential milestone payments of up to $180.0 million and tiered double-digit royalties based on net sales.

Under the agreement, we will be responsible for all regulatory interactions and for providing commercial 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 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.

Our Pipeline: Clinical-Stage Programs

Ovaprene

In October 2022, we announced that the FDA approved an Investigational Device Exemption, or IDE, application allowing us to conduct a single arm, open-label pivotal contraceptive efficacy study of Ovaprene. The multi-center, non-comparative pivotal Phase 3 clinical study will evaluate Ovaprene's effectiveness as a contraceptive device along with its safety and usability over a 12-month (13 menstrual cycles) duration. If successful, the study is expected to support a premarket approval, or PMA, application to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene. Initiation of recruitment for the study is targeted for mid-2023.

There is no predicate device for Ovaprene (i.e., there is no existing FDA-approved product that the FDA can use to compare with Ovaprene). As such, Ovaprene will be reviewed via a PMA and not a 510(k) premarket submission. While the regulatory process for such a novel product can require more interactions and research to support FDA approval, the benefit is a clearly differentiated product. In order for the planned study to serve as the primary clinical support for a future marketing approval or clearance, the FDA provided additional study design considerations with the IDE approval letter. Implementing such study design considerations will further position the study to collect safety and effectiveness data to enable the preparation of, and to support the submission of, a PMA application. We are working with our collaborators at the National Institutes of Health, or NIH, and at Bayer to review and implement the FDA's study design considerations.

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 and the remaining amount is due in the second quarter of 2023. NICHD will be responsible for the other costs related to the conduct of the Phase 3 study and will manage the payment of expenses to the contract research organization for the study, the clinical sites, and other parties involved with the study.

Sildenafil Cream, 3.6%

In October 2022, subject screening for our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% was completed, allowing for a topline data announcement target of the second quarter of 2023.

The Phase 2b RESPOND study is a multi-center, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of Sildenafil Cream, 3.6% in premenopausal patients with female sexual arousal disorder, or FSAD. The primary efficacy endpoint of the study is a composite endpoint that includes patient-reported improvement in genital sensations of arousal and reduction in distress associated with FSAD. The study is designed to evaluate Sildenafil Cream, 3.6% compared to placebo cream over 12 weeks of dosing following both a non-drug and placebo run-in period.

In August 2022, we announced that, based on the results of an interim analysis to evaluate the relative magnitude of the treatment effect, we expected to complete enrollment in the Phase 2b RESPOND study with a revised projected number of subjects in the fourth quarter of 2022. The interim analysis was conducted by an independent third-party statistical resource and we, as well as our collaborator, Strategic Science & Technologies, LLC, continue to remain blinded to results of the study by treatment group. While the study was originally expected to randomize a minimum of 400 subjects into the double-blind dosing period from 40 to 50 sites in the U.S. to achieve 150 subjects per arm completing the 12-week double-blind dosing period, based on the analysis of unblinded data by the independent third-party statistical resource to evaluate the relative magnitude of the treatment effect, approximately 160 to 170 subjects are expected to complete the 12-week double-blind dosing period (approximately 80 to 85 subjects per arm). The reduction in the number of subjects should not be viewed as indicative of the magnitude of the treatment effect. The relative magnitude of the treatment effect seen in the interim analysis should not be viewed as predictive that topline data will show Sildenafil Cream, 3.6% achieved the efficacy endpoints of the Phase 2b RESPOND study.

DARE-HRT1

In October 2022, 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 was designed to evaluate the pharmacokinetics (PK) of two versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study also collected safety, usability, acceptability and symptom-relief data including the vasomotor symptoms (VMS) as well as the vaginal symptoms of menopause. The levels of estradiol released from both the lower and higher dose formulation of DARE-HRT1 evaluated in the study achieved statistically significant improvement in VMS as well as the genitourinary symptoms of menopause, and vaginal pH and maturation index. Menopausal symptoms, including hot flashes and night sweats, were reduced compared with baseline in both DARE-HRT1 dose groups ($p<0.01$). Participants also showed significant improvement from baseline in all measures surveyed on The Menopausal Quality of Life Survey (MENQOL), which surveys not only parameters of VMS, but also physical, psychosocial and sexual symptoms ($p<0.01$ on all domains). With DARE-HRT1 use, vaginal pH significantly decreased compared to baseline ($p<0.01$) and cytologic tests of the vaginal epithelium (vaginal maturation index) showed significant normalization (all p values <0.01 for increases in superficial cells, increases in intermediate cells and decreases in parabasal cells from baseline) among all participants. The most common genitourinary symptom, vaginal dryness, which was reported by 70% of participants at baseline, showed significant improvement in both DARE-HRT1 groups ($p<0.01$) and this subset also experienced significant decreases in vaginal pain with DARE-HRT1 use ($p<0.01$).

The study treatment was well tolerated with the types of most common adverse events consistent with other vaginal products. There were only two early discontinuations due to an adverse event, and no serious adverse events were reported. DARE-HRT1 had a high level of acceptability in the study, with 100% of subjects reporting that the IVR was comfortable to wear, and there were no reports of the IVR being expelled from the vagina during use. Additionally, over 95% of subjects stated they would be either somewhat or very likely to use the IVR for a women’s health condition or unrelated disease if needed. We anticipate that the topline PK data from the Phase 1/2 study will be available and reported later in the fourth quarter of 2022.

DARE-VVA1

In September 2021, we announced initiation of our Phase 1/2 clinical study of DARE-VVA1. The randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study will evaluate the safety, tolerability, PK, and pharmacodynamics (PD) of DARE-VVA1 in postmenopausal participants with moderate to severe VVA in 15 to 20 postmenopausal women, including a cohort of women with a history of hormone-receptor positive breast cancer, at three study sites. The study is being conducted by our wholly owned subsidiary in Australia. Eligible participants will be randomly allocated to one of five treatment groups (approximately five participants per group) that will evaluate four dose levels (1 mg, 5 mg, 10 mg, and 20 mg) and a placebo. Following a screening visit, DARE-VVA1 will be self-administered intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants will have serial blood sampling for PK analysis and undergo safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants will attend a safety follow-up visit. The primary endpoints of the study will evaluate the safety and tolerability of DARE-VVA1 by vaginal administration and determine the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints will evaluate the preliminary efficacy and PD of DARE-VVA1 in terms of the most bothersome symptom and changes in vaginal cytology and pH. We anticipate reporting topline data from the Phase 1/2 clinical study later in the fourth quarter of 2022.

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 2022.

ADARE-204 and ADARE-214

We are conducting development activities in preparation for Phase 1 clinical studies of ADARE-204 and ADARE-214. We do not expect to commence clinical development activities of these product candidates in 2022. We anticipate a Phase 1 clinical study of ADARE-204 and ADARE-214 by our wholly owned subsidiary in Australia in 2023.

Recent Events

Ovaprene IDE Application Approval for Phase 3 Clinical Study

As discussed above, in October 2022, the FDA approved our IDE application for a single arm, open-label pivotal contraceptive efficacy study of Ovaprene.

Positive Topline Data from DARE-HRT1 Phase 1/2 Clinical Study

As discussed above, in October 2022, we announced topline data from our Phase 1/2 clinical study of DARE-HRT1.

Receipt of Australia Research and Development Cash Credit

In October 2022, we received a research and development rebate from the government of Australia in the amount of approximately $786,000 for clinical work performed in Australia in 2021. The rebate is accounted for as an offset to research and development expense.

License Agreement with Hennepin Life Sciences to Expand Product Candidate Pipeline

In August 2022, we entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which we acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. Under the agreement, we received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. We agreed to make potential future milestone payments through the term of the license based on clinical, regulatory, and commercial events, and to pay royalties based on commercial sales. We are entitled to sublicense the rights granted to us under this agreement.

Receipt of Payment Under XACIATO License Agreement

As discussed above, in July 2022, we received the $10.0 million upfront payment from Organon under our XACIATO license agreement.

Receipt of Payment Under 2021 DARE-LARC1 Grant Agreement

In July 2022, we received approximately $8.0 million from the Foundation under the 2021 DARE-LARC1 Grant Agreement.

Increase in Authorized Shares of Common Stock

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

Financial Overview

Revenue

To date we have generated $10.0 million in revenue, all of which represents the upfront payment under our license agreement with Organon to commercialize XACIATO, which is recognized as license fee revenue. In the future, we may generate revenue from royalties and commercial milestones based on the net sales of XACIATO, from product sales of other approved products, if any, and from license fees, milestone payments, research and development payments in connection with strategic collaborations. 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 product candidates in a timely manner, or to receive regulatory approval for such product candidates, our ability to generate future revenue and our results of operations would be materially adversely affected.

Research and Development Expenses

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

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

In 2021, our research and development expenses consisted primarily of costs associated with the continued development of XACIATO, Ovaprene and Sildenafil Cream, 3.6%, and during the first three quarters of 2022, our research and development expenses consisted primarily of costs associated with the continued development of Ovaprene and Sildenafil Cream 3.6%. We expect research and development expenses to increase in the future as we continue to invest in the development of and seek regulatory approval for our clinical-stage and Phase 1-ready product candidates and as any other potential product candidates we may develop are advanced into and through clinical trials in the pursuit of regulatory approvals. Such activities will require a significant increase in investment in regulatory support, clinical supplies, inventory build-up related costs, and the payment of success-based milestones to licensors. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to, among other factors, license fee and/or milestone payments.

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

License Fee Expense

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

General and Administrative Expense

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

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 unaudited condensed consolidated interim 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 2021 10-K, and Note 2 to our unaudited condensed consolidated financial statements contained in this report.

Results of Operations

Comparison of Three Months Ended September 30, 2022 and 2021 (Unaudited)

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

	Three Months Ended September 30,		Change	
	2022	2021	$	%
Revenues:				
License fee revenue	$ —	$ —	$ —	— %
Total revenue	—	—	—	— %
Operating expenses:				
General and administrative	2,651,543	2,211,334	440,209	20 %
Research and development	4,462,250	10,432,603	(5,970,353)	(57)%
License fee expense	25,000	25,000	—	— %
Total operating expenses	7,138,793	12,668,937	(5,530,144)	(44)%
Loss from operations	(7,138,793)	(12,668,937)	5,530,144	(44)%
Other income	118,950	1,508	117,442	7788 %
Net loss	$ (7,019,843)	$ (12,667,429)	$ 5,647,586	(45)%
Other comprehensive loss:				
Foreign currency translation adjustments	(230,748)	(63,281)	(167,467)	265 %
Comprehensive loss	$ (7,250,591)	$ (12,730,710)	$ 5,480,119	(43)%

General and administrative expenses

The increase of approximately $0.4 million in general and administrative expenses for the three months ended September 30, 2022 as compared to the three months ended September 30, 2021 was primarily attributable to an increase in professional services expense of approximately $339,000. Also contributing to the increases were increases in (i) general corporate overhead of approximately $129,000, (ii) stock-based compensation expense of approximately $94,000, and (iii) personnel costs of approximately $36,000. These increases were partially offset by decreases in (a) commercial-readiness expenses of approximately $140,000, and (b) rent and facilities expenses of $38,000.

We expect an increase in general and administrative expenses of approximately 25% in 2022 compared to 2021 primarily due to increased personnel expenses and other general corporate overhead. Our general and administrative expenses in 2021 were approximately $8.4 million. Our 2022 general and administrative expenses will include costs related to commercial-readiness activities and obtaining commercial supplies of XACIATO from our contract manufacturer. 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., which is expected to occur in the first half of 2023, and royalty payments at rates in the high single-digit to low double-digits based on annual net sales of XACIATO.

Research and development expenses

The decrease of approximately $6.0 million in research and development expenses for the three months ended September 30, 2022 as compared to the three months ended September 30, 2021 was attributable to decreases in (i) costs for two of our clinical-stage product candidates, Sildenafil Cream 3.6% and Ovaprene, of approximately $4.8 million related to the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene, (ii) costs related to development activities for XACIATO of approximately $823,000 as a result of the completion of the Phase 3 clinical trial for XACIATO in December 2020, (iii) costs related to development activities for our preclinical programs of approximately $388,000, (iv) costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $277,000, and (v) rent and facilities expenses of approximately $54,000. These decreases were partially offset by increases in (a) personnel costs of approximately $358,000, and (b) stock-based compensation expense of approximately $23,000.

We expect our research and development expenses to remain approximately flat in 2022 compared to 2021. Our research and development expenses in 2021 were approximately $30.6 million. We expect the pace and extent of our research and development activities and, therefore, our research and development spend, to vary across fiscal quarters, making them difficult to predict. We expect our research and development spend for 2022 to be less than previously anticipated due to changes in the pace and extent of research and development activities related to our clinical-stage and Phase 1-ready product candidates. Factors that impact the pace and extent of our research and development activities and 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. In regard to Sildenafil Cream, 3.6%, we anticipate that the total cost of the Phase 2b RESPOND clinical trial will be approximately $20.0 million, approximately $9.5 million of which was recorded in prior fiscal years.

License fee expense

For each of the three months ended September 30, 2022 and September 30, 2021, 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 unaudited condensed consolidated financial statements contained in this report.

Other income

The increase of $117,442 in other income for the three months ended September 30, 2022 as compared to the three months ended September 30, 2021 was primarily due to an increase in interest earned on cash balances in the current period.

Comparison of Nine Months Ended September 30, 2022 and 2021 (Unaudited)

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

	Nine months ended September 30,		Change	
	2022	2021	$	%
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	8,014,424	5,949,299	2,065,125	35 %
Research and development	17,065,497	23,501,098	(6,435,601)	(27)%
License fee expense	75,000	75,000	—	— %
Total operating expenses	25,154,921	29,525,397	(4,370,476)	(15)%
Loss from operations	(15,154,921)	(29,525,397)	14,370,476	(49)%
Other income	150,406	1,686	148,720	8821 %
Gain on extinguishment of note payable	—	369,887	(369,887)	(100)%
Net loss	$ (15,004,515)	$ (29,153,824)	$ 14,149,309	(49)%
Other comprehensive loss:				
Foreign currency translation adjustments	(375,767)	(79,002)	(296,765)	376 %
Comprehensive loss	$ (15,380,282)	$ (29,232,826)	$ 13,852,544	(47)%

Revenues

License fee revenue relates to our license agreement with Organon to commercialize XACIATO. We earned $10.0 million in revenue during the nine months ended September 30, 2022, related to the transfer of the license and related know-how to Organon upon effectiveness of the agreement on June 30, 2022. We do not expect to receive additional revenue under this agreement in 2022. If the first commercial sale of XACIATO in the U.S. occurs in the first half of 2023 as expected, we should receive an additional $2.5 million under this agreement as a milestone payment following such first sale.

We did not recognize any revenue for the nine months ended September 30, 2021.

General and administrative expenses

The increase of approximately $2.1 million in general and administrative expenses for the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 was primarily attributable to increases in (i) professional services expense of approximately $1.2 million, (ii) general corporate overhead expenses of $316,000, (iii) stock-based compensation expense of approximately $291,000, (iv) personnel costs of approximately $189,000, and (v) commercial-readiness expenses of approximately $73,000.

Research and development expenses

The decrease of approximately $6.4 million in research and development expenses for the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 was attributable to decreases in (i) costs related to manufacturing and regulatory affairs activities for Ovaprene of approximately $3.1 million, (ii) costs related to development activities for XACIATO of approximately $2.5 million as a result of the completion of the Phase 3 clinical trial for XACIATO in December 2020, (iii) costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $1.1 million, and (iv) costs related to development activities for our preclinical programs of approximately $712,000. Such decreases were partially offset by increases in (a) personnel costs of approximately $689,000, (b) stock-based compensation expense of approximately $125,000, and (c) rent and facilities expenses of $107,000 attributable to the allocation of a portion of rent and facilities expense included in general and administrative in 2021 to research and development in 2022.

License fee expense

For each of the nine months ended September 30, 2022 and September 30, 2021, we accrued $75,000 of the $100,000 annual license maintenance fee payable under our license agreement related to DARE-HRT1.

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

Other income

The increase of $148,720 in other income for the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 was primarily due to an increase in interest earned on cash balances in the current period.

Gain on extinguishment of note payable

The $369,887 recorded as a gain on extinguishment of note payable and debt forgiveness income in 2021 represents the forgiveness of all the principal and accrued interest of the loan we obtained under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

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. We have a history of losses from operations, we expect negative cash flows from our operations to continue for the foreseeable future, and we expect that our net losses will continue for at least the next several years as we develop and seek to bring to market our existing product candidates and as we seek to potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

At September 30, 2022, our accumulated deficit was approximately $125.1 million, our cash and cash equivalents were approximately $40.4 million, our deferred grant funding liability under our grant agreement related to DARE-LARC1 was $14.8 million (representing grant funds received that may be applied solely for the development of DARE-LARC1 and which are included in cash and cash equivalents), and our working capital was approximately $26.7 million. We incurred a loss from operations of approximately $15.0 million and had negative cash flow from operations of approximately $12.2 million during the nine months ended September 30, 2022.

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-parties 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.

We expect to incur significant losses from operations and negative cash flows from operations in 2022 and 2023, driven by our research and development expenses. We anticipate our expenses, and in particular our research and development expenses, to be significant in 2023 as they were in 2022 as we continue to develop our product candidates, with a focus on our candidates that have reached the human clinical study development phase. Under the terms of our license agreement with Organon, Organon will purchase all of its product requirements of 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 of providing XACIATO commercial supplies will have a material impact on our cash resources and requirements.

Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. 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. During the nine months ended September 30, 2022, we received $10.0 million in license fee revenue under our license agreement for XACIATO, approximately $8.0 million under our grant agreement for pre-clinical development of DARE-LARC1, and we generated approximately $1.2 million in net proceeds from sales of our common stock. Subsequent to September 30, 2022, we received a research and development rebate from the government of Australia in the amount of approximately $786,000 for clinical work performed in Australia in 2021.

We will need to raise substantial additional capital to continue to fund our operations and to successfully execute our current business strategy. We will continue to seek to raise capital through the sale of shares of our common stock under our ATM sales agreements, however, when we effect such sales and the amount of shares we can sell depends on a variety of factors including, among others, market conditions, the trading price of our common stock, and our determination as to the appropriate sources of funding for our operations. For the foreseeable future, we will evaluate and may pursue a variety of capital raising options on an on-going basis, including equity and 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. The amount and timing of our capital needs have been and will continue to depend highly on many factors, including the product development programs we choose to pursue, the pace and results of our clinical development efforts, and the nature and extent of expansion of our product candidate portfolio, if any. 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.

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. In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders, and debt financings may subject us to restrictive covenants, operational restrictions and security interests in our assets. If we cannot raise capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. See the risk factor in Part I, Item 1A of our 2021 10-K titled *We will need to raise additional capital to continue our operations and execute our business strategy*.

Cash Flows

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

	Nine months ended September 30,	
	2022	2021
Net cash used in operating activities	$ (12,191,757)	$ (18,848,138)
Net cash used in investing activities	(60,372)	(14,524)
Net cash provided by financing activities	1,343,355	59,842,978
Effect of exchange rate changes on cash and cash equivalents	(375,767)	(79,002)
Net increase (decrease) in cash and cash equivalents	$ (11,284,541)	$ 40,901,314

Net cash used in operating activities

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

Cash used in operating activities for the nine months ended September 30, 2021 included the net loss of $29.2 million, decreased by non-cash stock-based compensation expense of approximately $1.2 million and increased by the non-cash gain on the extinguishment of the note payable and accrued interest of approximately $370,000. Components providing operating cash were an increase in deferred grant funding of approximately $9.6 million, an increase in accrued expenses of approximately $0.6 million, and a decrease in other receivables of approximately $0.3 million related to the receipt of the 2020 Australian cash research and development tax credit in April 2021. Components reducing operating cash were an increase in prepaid expenses of approximately $662,000 and a decrease in accounts payable of approximately $416,000.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2022 and September 30, 2021 was approximately $60,000 and $14,500, respectively.

Net cash provided by financing activities

Cash provided by financing activities for the nine months ended September 30, 2022 and September 30, 2021 consisted of approximately $1.3 million and $59.8 million in the aggregate, respectively, primarily from sales of our common stock under our ATM sales agreement.

License and Royalty Agreements

We agreed to make royalty and milestone payments under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream, 3.6%, and under other agreements related to our other clinical and preclinical candidates. For further discussion of these potential payments, see Note 3 to our unaudited condensed consolidated financial statements contained in this report.

Other Contracts

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on an evaluation performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of September 30, 2022 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 2021 10-K, in addition to other information in this report, before investing in our common stock. The occurrence of any of these risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. There have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in our 2021 10-K other than as described below.

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

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

The Biden Administration has also indicated that lowering prescription drug prices is a priority, and the Department of Health and Human Services, or DHHS, released a drug pricing plan in September 2021 that indicates the Administration supports aggressive actions such as allowing DHHS to negotiate the cost of Medicare Part B and D drugs. Such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions. Most recently, on August 16, 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, the Centers for Medicare and Medicaid Services, or CMS, will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. It is unclear how these forthcoming changes in the way that CMS does business with certain members of the biopharmaceutical industry may impact coverage or reimbursement decisions across the industry as a whole.

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

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

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

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.
(b) None.

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
3.1	Restated Certificate of Incorporation, as amended to date	10-Q	001-36395	8/9/22	3.1	
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

Furnished herewith. This certification is being furnished solely to accompany this report pursuant to U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated herein by reference into any filing of the registrant whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Daré Bioscience, Inc.

Date: November 10, 2022

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

Date: November 10, 2022

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

Exhibit 31.1

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2022

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

Exhibit 31.2

CERTIFICATIONS

I, Lisa Walters-Hoffert, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2022

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: November 10, 2022

/s/ Sabrina Martucci Johnson

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: November 10, 2022

/s/ Lisa Walters-Hoffert

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