UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from _____ to _____

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

Delaware	**Commission File No. 001-36395**	**20-4139823**
(State or Other Jurisdiction of Incorporation)		(IRS Employer Identification No.)
3655 Nobel Drive, Suite 260 San Diego, CA	**(858) 926-7655**	**92122**
(Address of Principal Executive Offices)	(Registrant's telephone number, including area code)	(Zip Code)

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

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

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

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

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

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

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

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

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

As of August 9, 2021, 70,521,979 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 costs, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," project," "target," "tend to," or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors described in Part 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 continue as a going concern;*
- *Inability to raise additional capital, under favorable terms or at all, including as a result of the effects of the COVID-19 pandemic;*
- *Inability to successfully attract partners and enter into collaborations relating to the development and/or commercialization of our product candidates on a timely basis or on acceptable terms, or at all;*
- *A decision by Bayer HealthCare LLC to discontinue its commercial interest in Ovaprene® and/or to terminate our license agreement;*
- *Inability or an increase in projected costs to timely develop, obtain regulatory approval for and commercialize our product candidates;*
- *Failure or delay in starting, conducting and completing clinical trials or obtaining United States Food and Drug Administration, or FDA, or foreign regulatory approval for our product candidates in a timely manner, including as a result of matters beyond our control such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic;*
- *A change in the FDA Center assigned primary oversight responsibility for our combination product candidates;*
- *A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FDA's 505(b)(2) pathway;*
- *Unsuccessful clinical trial outcomes stemming from clinical trial designs, failure to enroll a sufficient number of patients, higher than anticipated patient dropout rates, failure to meet established clinical endpoints, undesirable side effects and other safety concerns;*
- *Reaching a conclusion regarding the efficacy or safety of a product candidate following full evaluation of complete clinical study data that is materially different from topline study results we may report;*
- *Communication from the FDA or another regulatory authority that it does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that it interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *Negative publicity concerning the safety and efficacy of our product candidates, or of product candidates being developed by others that share characteristics similar to our candidates;*
- *Inability to demonstrate sufficient efficacy of our product candidates;*

- *Failure to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates due to limited financial resources;*
- *Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;*
- *Monetary obligations and other requirements in connection with our exclusive, in-license agreements covering the patents and related intellectual property related to our product candidates, or our merger or asset purchase agreements relating to the acquisition of our product candidates;*
- *Developments by our competitors that make our product candidates less competitive or obsolete;*
- *Dependence on third parties to conduct nonclinical studies and clinical trials of our product candidates;*
- *Dependence on third parties to supply and manufacture clinical trial materials and, if any of our candidates are approved, commercial product, including components of our products as well as the finished product, in accordance with current good manufacturing practices and in the quantities needed;*
- *Dependence on third parties to commercialize, or assist us in commercializing, our products, when and if any receive regulatory approval.*
- *Cyber-attacks, security breaches or similar events compromising our technology systems or the technology systems of third parties on which we rely;*
- *Interruptions in, or the complete shutdown of, the operations of third parties on which we rely, including clinical sites, manufacturers, suppliers, and other vendors, from matters beyond their control, such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic, and our lack of recourse against such third parties if their inability to perform is excused under the terms of our agreements with such parties;*
- *Failure of our product candidates, if approved, to gain market acceptance or obtain adequate coverage for third party reimbursement;*
- *A reduction in demand for contraceptives caused by an elimination of current requirements that health insurance plans cover and reimburse certain FDA-cleared or approved contraceptive products without cost sharing;*
- *Uncertainty as to whether health insurance plans will cover our product candidates even if we successfully develop and obtain regulatory approval for them;*
- *Unfavorable or inadequate reimbursement rates for our product candidates set by the United States government and other third-party payers even if they become covered products under health insurance plans;*
- *Difficulty in introducing branded products in a market made up of generic products;*
- *Inability to adequately protect or enforce our, or our licensor's, intellectual property rights;*
- *Lack of patent protection for the active ingredients in certain of our product candidates which could expose those product candidates to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in pre-clinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could subject us to securities class-action litigation;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*

- *Litigation or public concern about the safety of our potential products;*
- *Strict government regulations on our business, including various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act;*
- *Regulations governing the production or marketing of our product candidates;*
- *Loss of, or inability to attract, key personnel; and*
- *Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.*

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

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

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 9,111,741	$ 4,669,467
Other receivables	2,955,425	460,168
Prepaid expenses	1,992,054	1,854,277
Total current assets	14,059,220	6,983,912
Property and equipment, net	24,907	37,930
Other non-current assets	738,283	528,870
Total assets	$ 14,822,410	$ 7,550,712
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 216,043	$ 1,021,333
Accrued expenses	4,369,901	3,359,718
Deferred grant funding	—	1,564,553
Note payable	—	367,285
Contingent consideration	1,000,000	1,000,000
Current portion of lease liabilities	418,946	347,712
Total current liabilities	6,004,890	7,660,601
Deferred license revenue	1,000,000	1,000,000
Lease liabilities long-term	73,516	41,844
Total liabilities	7,078,406	8,702,445
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value, 5,000,000 shares authorized; None issued and outstanding	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized; 57,409,523 and 41,596,253 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	5,741	4,159
Accumulated other comprehensive loss	(107,109)	(91,388)
Additional paid-in capital	95,762,564	70,366,293
Accumulated deficit	(87,917,192)	(71,430,797)
Total stockholders' equity (deficit)	7,744,004	(1,151,733)
Total liabilities and stockholders' equity (deficit)	$ 14,822,410	$ 7,550,712

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Operating expenses				
General and administrative	$ 1,797,637	$ 1,557,548	$ 3,737,965	$ 3,419,313
Research and development	7,340,289	5,547,450	13,068,495	7,927,254
License fees	25,000	20,833	50,000	33,333
Total operating expenses	9,162,926	7,125,831	16,856,460	11,379,900
Loss from operations	(9,162,926)	(7,125,831)	(16,856,460)	(11,379,900)
Other income	175	1,618	178	3,439
Gain on extinguishment of note payable	—	—	$ 369,887	—
Net loss	$ (9,162,751)	$ (7,124,213)	$ (16,486,395)	$ (11,376,461)
Foreign currency translation adjustments	(8,880)	12,090	(15,721)	(10,854)
Comprehensive loss	$ (9,171,631)	$ (7,112,123)	$ (16,502,116)	$ (11,387,315)
Loss per common share - basic and diluted	$ (0.18)	$ (0.27)	$ (0.35)	$ (0.45)
Weighted average number of common shares outstanding:				
Basic and diluted	50,436,593	26,710,750	47,485,980	25,255,073

See accompanying notes.

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

Six Months Ended June 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**

Six Months Ended June 30, 2020

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2019	**19,683,401**	**$ 1,968**	**$ 44,564,674**	**$ (102,625)**	**$ (44,023,191)**	**$ 440,826**
Stock-based compensation	—	—	160,841	—	—	160,841
Issuance of common stock, net of issuance costs	3,308,003	331	5,222,356	—	—	5,222,687
Issuance of common stock from the exercise of warrants	1,699,000	170	1,664,850	—	—	1,665,020
Stock option exercised	10,149	1	—	—	—	1
Net loss	—	—	—	—	(4,252,248)	(4,252,248)
Foreign currency translation adjustments	—	—	—	(22,944)	—	(22,944)
Balance at March 31, 2020	**24,700,553**	**$ 2,470**	**$ 51,612,721**	**$ (125,569)**	**$ (48,275,439)**	**$ 3,214,183**
Stock-based compensation	—	—	186,859	—	—	186,859
Issuance of common stock, net of issuance costs	3,823,451	382	4,021,954	—	—	4,022,336
Net loss	—	—	—	—	(7,124,213)	(7,124,213)
Foreign currency translation adjustments	—	—	—	12,090	—	12,090
Balance at June 30, 2020	**28,524,004**	**$ 2,852**	**$ 55,821,534**	**$ (113,479)**	**$ (55,399,652)**	**$ 311,255**

See accompanying notes.

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

	Six months ended June 30,	
	2021	**2020**
Operating activities:		
Net loss	$ (16,486,395)	$ (11,376,461)
Non-cash adjustments reconciling net loss to operating cash flows:		
Depreciation	13,023	23,929
Stock-based compensation	771,389	347,700
Non-cash operating lease cost	(45,270)	(90,080)
Gain on extinguishment of notes payable and accrued interest	(369,887)	—
Changes in operating assets and liabilities:		
Other receivables	(2,495,256)	378,077
Prepaid expenses	(137,777)	(1,144,246)
Other non-current assets	(61,237)	78,513
Accounts payable	(805,291)	630,899
Accrued expenses	1,012,785	(457,901)
Deferred grant funding	(1,564,553)	(74,894)
Deferred license revenue	—	1,000,000
Net cash used in operating activities	(20,168,469)	(10,684,464)
Investing activities:		
Purchases of property and equipment	—	(15,246)
Net cash used in investing activities	—	(15,246)
Financing activities:		
Net proceeds from issuance of common stock	24,576,064	9,245,023
Proceeds from the exercise of common stock warrants	50,400	1,665,020
Proceeds from the exercise of stock options	—	1
Proceeds from issuance of note payable	—	367,285
Net cash provided by financing activities	24,626,464	11,277,329
Effect of exchange rate changes on cash and cash equivalents	(15,721)	(10,854)
Net change in cash and cash equivalents	4,442,274	566,765
Cash and cash equivalents, beginning of period	4,669,467	4,780,107
Cash and cash equivalents, end of period	$ 9,111,741	$ 5,346,872
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ 308,533	$ —

See accompanying notes.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Daré Bioscience, Inc. is a clinical-stage biopharmaceutical company committed to advancing innovative products for women's health. Daré Bioscience, Inc. and its wholly owned subsidiaries operate in one segment. In this report, the "Company" refers collectively to Daré Bioscience, Inc. and its wholly owned subsidiaries, unless otherwise stated or the context otherwise requires.

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

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

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

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

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

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

- **DARE-LARC1**, a contraceptive implant with a woman-centered design that has the potential to be a long-acting, convenient and user-controlled contraceptive option;
- **ADARE-204 and ADARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

The Company's primary operations have consisted of, and are expected to continue to consist primarily of, research and development activities to advance its product candidates through clinical development and regulatory approval. The Company has focused on the advancement of DARE-BV1, Ovaprene, and Sildenafil Cream, 3.6%.

To date, the Company has not obtained any regulatory approvals for any of its product candidates, commercialized any of its product candidates or generated any revenue. The Company is subject to several risks common to clinical-stage 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. The Company is also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, and product liability.

The effect of the COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain an evolving and uncertain risk to the Company's business, operating results, financial condition and stock price. Challenges to vaccination efforts, variants of the virus that causes COVID-19 circulating globally, including within the U.S., and other causes of virus spread have resulted in, and may continue to result in, local, state, federal and foreign governments reimposing restrictions in various geographies. To date, neither government-imposed restrictions or other governmental actions nor the Company's remote working arrangements or those of its third-party service providers and contract manufacturers have materially affected the Company's ability to operate its business, and the Company has been able to advance its portfolio of product candidates in meaningful ways during the pandemic, including by commencing and completing a Phase 3 clinical trial of DARE-BV1 during 2020. However, the effects of the pandemic could have a material adverse impact on the Company's business, operating results and financial condition, including, without limitation, by increasing the anticipated aggregate costs and timelines for the development and marketing approval of the Company's product candidates. For example, the pace of enrollment of participants in the Company's ongoing clinical trial for Sildenafil Cream, 3.6% at certain sites has recently declined because of those sites adhering to governmental guidelines recommending reductions or changes in their operations intended to reduce the spread of COVID-19. The commencement and/or completion of clinical trials for the Company's product candidates, including Ovaprene, could also be delayed for similar reasons or because of individuals being less inclined to participate in or complete trials that require multiple clinic visits as a result of increased transmissibility of the virus that causes COVID-19 or due to a spike in hospitalizations in the U.S. that causes healthcare industry resources to be diverted from participating in research and development activities for investigational products unrelated to COVID-19 or because the operations of contract manufacturers of clinical supplies are disrupted due to the effects of COVID-19 and are unable to fulfill the Company's needs. Conversely, continued re-opening of the U.S. and global economies may delay enrollment in clinical trials for Sildenafil Cream, 3.6% and Ovaprene as individuals gain more freedom to travel and participate in other activities that have not been available to them since the beginning of the pandemic and may be less inclined to participate in or complete studies that require multiple clinic visits. In addition, the effects of the pandemic could adversely impact the Company's ability to raise capital when needed or on terms favorable or acceptable to the Company. Continued uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, workplace environments and capital markets, preclude any prediction as to the ultimate effect of the pandemic on the Company's business. See also the risk factor titled, *The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs,* in Part II, ITEM 1A, Risk Factors, of this report.

Going Concern

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

As of June 30, 2021, the Company had an accumulated deficit of approximately $87.9 million, cash and cash equivalents of approximately $9.1 million, and working capital of approximately $8.1 million. For the six months ended June 30, 2021, the Company incurred a net loss of $16.5 million and had negative cash flow from operations of approximately $20.2 million.

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

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

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

Based on the Company's current operating plan estimates, the Company does not have sufficient cash to satisfy its working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. The Company needs to raise substantial additional capital to continue to fund its operations and to successfully execute its current operating plan, including the development of its product candidates. The Company is currently evaluating a variety of capital raising options, including equity and debt financings, government or other grant funding, collaborations and strategic alliances and other similar types of arrangements to cover its operating expenses, including the development of its product candidates and any future product candidates it may license or otherwise acquire. The amount and timing of the Company's capital needs have been and will continue to depend highly on many factors, including the product development programs the Company chooses to pursue and the pace and results of its clinical development efforts. If the Company raises capital through collaborations, strategic alliances or other similar types of arrangements, it may have to relinquish, on terms that are not favorable to the Company, rights to some of its technologies or product candidates it would otherwise seek to develop or commercialize. There can be no assurances that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders, including because developments in the COVID-19 pandemic could adversely impact investor sentiment. In addition, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders, and debt financings may subject the Company to restrictive covenants, operational restrictions and security interests in 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 condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company’s significant accounting policies are described in Note 1 to the consolidated financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2020, or the 2020 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 30, 2021. Since the date of those consolidated financial statements, there have been no material changes to the Company’s 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 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 2020 10-K.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in other non-current assets, current portion of lease liabilities, and lease liabilities long-term on the Company's condensed consolidated balance sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date based on the present value of lease payments over the lease term. If the lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease assets also includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease and the related payments are only included in the lease liability when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. (See Note 6, Leased Properties.)

Fair Value of Financial Instruments

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

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

The following tables present the classification within the fair value hierarchy of financial assets and liabilities that are remeasured on a recurring basis as of June 30, 2021 and December 31, 2020. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) as of June 30, 2021 or December 31, 2020.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at June 30, 2021				
Current assets:				
Cash equivalents [1]	$ 7,666,170	$ —	$ —	$ 7,666,170
Current liabilities:				
Current portion of contingent consideration [2]	$ —	$ —	$ 1,000,000	$ 1,000,000
Balance at December 31, 2020				
Current assets:				
Cash equivalents [1]	$ 2,823,099	$ —	$ —	$ 2,823,099
Other non-current liabilities:				
Current portion of contingent consideration [2]	$ —	$ —	$ 1,000,000	$ 1,000,000

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

[2] Represents the estimated fair value of the contingent consideration potentially payable by the Company related to an acquisition completed in November 2019, as described in Note 3.

Revenue Recognition

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

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

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

License Fees. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. To date, the Company has not recognized any license fee revenue.

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.

Bayer License. In January 2020, the Company entered into a license agreement with Bayer HealthCare LLC, or Bayer, regarding the further development and commercialization of Ovaprene in the U.S. Upon execution of the agreement, the Company received a $1.0 million upfront non-refundable license fee payment from Bayer. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $20.0 million. The Company concluded that there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (1) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (2) the termination of the agreement. As of June 30, 2021, 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 June 30, 2021 and December 31, 2020.

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

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

3. LICENSE AND COLLABORATION AGREEMENTS

Out-License Agreements

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

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

Efforts. The Company is responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer is supporting the Company in development and regulatory activities by providing up to two full-time equivalents with expertise in clinical, regulatory, preclinical, commercial, CMC and product supply matters in an advisory capacity. After payment of the $20.0 million fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

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

In-License Agreements

Hammock/MilanaPharm Assignment and License Agreement

In December 2018, the Company entered into (a) an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and (b) a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, the Company acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In DARE-BV1, this proprietary technology is formulated with clindamycin for the treatment of bacterial vaginosis. In December 2019, the Company entered into amendments to each of the Assignment Agreement and License Amendment.

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

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

Milestone Payments. The Company will pay to MilanaPharm (1) up to $300,000 in the aggregate upon achievement of certain clinical and regulatory development milestones, $50,000 of which was paid during the second quarter of 2020, and (2) up to $1.75 million in the aggregate upon achieving certain commercial sales milestones. See Note 10.

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

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

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

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

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

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

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

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

Milestone Payments. The Company will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $250,000 of which was paid during the second quarter of 2021.

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

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene and must meet certain minimum spending amounts per year, and $5.0 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

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

Royalty Payments. After the commercial launch of Ovaprene, the Company will pay to ADVA-Tec royalties based on aggregate annual net sales of Ovaprene in specified regions, at a royalty rate that will vary between 1% and 10% and will increase based on various net sales thresholds.

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

SST License and Collaboration Agreement

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

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

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

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

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

Royalty Payments. SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

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

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

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

Catalent JNP License Agreement

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

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

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

Milestone Payments. The Company must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the agreement. See Note 10.

Royalty Payments. During the royalty term, the Company will pay Catalent mid-single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, the Company will pay Catalent a low double-digit percentage of all sublicense income the Company receives for the sublicense of rights under the agreement to a third party.

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

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

Adare Development and Option Agreement

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

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

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

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

Acquired Products

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.

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

The Company also agreed to pay the following additional consideration to 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 annual net sales of such products, subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. The Company agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to DARE-LARC1. On June 30, 2021, a total of $1.25 million of that potential additional 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 recorded on the Company's consolidated balance sheets in accrued expenses. See Notes 7 and 10.

Pear Tree Acquisition

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

Milestone Payments. The Company must make contingent payments to the Pear Tree former stockholders and their representatives, or the Holders, that are based on achieving certain clinical, regulatory and commercial milestones, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock.

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

4. STOCK-BASED COMPENSATION

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan, or the ESPP, became effective in April 2014, but no offering period has been initiated thereunder since January 2017. There was no stock-based compensation related to the ESPP for the six months ended June 30, 2021 or June 30, 2020.

Amended and Restated 2014 Stock Incentive Plan

The Company maintains the Amended and Restated 2014 Plan, or the Amended 2014 Plan, which provides 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 increases annually on the first day of each fiscal year until, and including, the fiscal year ending December 31, 2024 by the least of (i) 2,000,000, (ii) 4% of the number of outstanding shares of common stock on such date, or (iii) an amount determined by the Company's board of directors. On January 1, 2021, the number of authorized shares increased by 1,663,850 to 2,168,366, which increase represented 4% of the number of outstanding shares of common stock on such date.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Amended 2014 Plan and related information for the six months ended June 30, 2021. The exercise price of all options granted during the six months ended June 30, 2021 was equal to the market value of the Company's common stock on the date of grant. As of June 30, 2021, unamortized stock-based compensation expense of $4,391,749 will be amortized over a weighted average period of 3.06 years. At June 30, 2021, 298,291 shares of common stock were reserved for future awards granted under the Amended 2014 Plan.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2020	2,786,591	$ 1.16
Granted	1,870,075	2.38
Exercised	—	—
Canceled/forfeited	—	—
Expired	—	—
Outstanding at June 30, 2021	4,656,666	$ 1.65
Exercisable at June 30, 2021	1,801,414	$ 1.40

Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 129,397	$ 59,713	$ 245,022	$ 106,093
General and administrative	$ 276,081	$ 127,146	$ 526,367	$ 241,607
Total	$ 405,478	$ 186,859	$ 771,389	$ 347,700

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the six months ended June 30, 2021 are as follows:

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Expected life in years	5.7	6.0
Risk-free interest rate	0.87%	0.64%
Expected volatility	124%	122%
Forfeiture rate	0.0%	0.0%
Dividend yield	0.0%	0.0%
Weighted-average fair value of options granted	$1.26	$2.06

5. STOCKHOLDERS' EQUITY

April 2021 ATM Sales Agreement

In April 2021, the Company entered into a sales agreement with SVB Leerink LLC to sell shares of its common stock from time to time through an ATM equity offering program under which SVB Leerink 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 three months ended June 30, 2021, the Company sold approximately 7.7 million shares of common stock under this agreement for gross proceeds of approximately $10.7 million and incurred offering expenses of approximately $363,000.

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 our common stock from time to time in an "at the market offerings" of equity securities (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act) through Wainwright, acting as sales agent. In accordance with the agreement, on March 29, 2021, we provided notice to Wainwright to terminate the agreement. The agreement terminated on April 3, 2021. Under the agreement, Wainwright was entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold under the agreement and we provided Wainwright with customary indemnification rights.

During the six months ended June 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 $245,000. During the six months ended June 30, 2020, the Company sold approximately 6.0 million shares under this agreement for gross proceeds of approximately $8.4 million and incurred offering expenses of approximately $338,000.

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 has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of the Company's common stock. Such sales of common stock by the Company may occur from time to time, at the Company's sole discretion, subject to certain limitations, until May 19, 2023. On April 22, 2020, in accordance with the Purchase Agreement, the Company issued 285,714 shares of its common stock, or the Commitment Shares, to Lincoln Park in consideration for its commitment to purchase shares under the Purchase Agreement. The Company filed a registration statement on Form S-1 (File No. 333-237954) to register the resale by Lincoln Park of up to 7.5 million shares of the Company's common stock issued or issuable to Lincoln Park under the Purchase Agreement, including the Commitment Shares, and such registration statement was declared effective by the SEC on May 12, 2020. The Company filed a registration statement on Form S-1 (File No. 333-251599) to register the resale by Lincoln Park of up to 6.4 million additional shares of the Company's common stock issued or issuable to Lincoln Park under the Purchase Agreement, and such registration statement was declared effective by the SEC on January 7, 2021.

The Company incurred legal, accounting, and other fees related to the Purchase Agreement of approximately $374,000. These costs are amortized and expensed as shares are sold under the Purchase Agreement and as of June 30, 2021 there were no unamortized costs. During the six months ended June 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. As of June 30, 2021, the Company has sold and Lincoln Park has purchased a total of $15.0 million of the Company's common stock under the Purchase Agreement, and no more shares of common stock may be sold by the Company to Lincoln Park under the Purchase Agreement.

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 six months ended June 30, 2021, warrants to purchase an aggregate of 52,500 shares of common stock were exercised for gross proceeds of approximately $50,000. During the six months ended June 30, 2020, warrants to purchase an aggregate of 1,699,000 shares of common stock were exercised for gross proceeds of approximately $1.7 million. As of June 30, 2021, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
2,906	$	120.40	12/01/2021
3,737	$	120.40	12/06/2021
6,500	$	10.00	04/04/2026
1,843,000	$	0.96	02/15/2023
1,856,143			

6. LEASED PROPERTIES

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018. In January 2021, the Company exercised its option to extend the term of the lease for one year such that the term now expires July 31, 2022.

MBI, a wholly owned subsidiary the Company acquired in November 2019, leases general office space in Lexington, Massachusetts and warehouse space in Billerica, Massachusetts. The Lexington lease commenced on July 1, 2013. In January 2021, the Company entered into an amendment to extend the term of the lease for one year such that the term now expires on September 30, 2022. The Billerica lease commenced on October 1, 2016 and terminates on March 31, 2022.

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

The leases do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company uses an incremental borrowing rate of 7% for operating leases that commenced prior to January 2019 (and all of the Company's operating leases commenced prior to such date). The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At June 30, 2021, the Company reported operating lease ROU assets of approximately $388,000 in other non-current assets, and $419,000 and $73,000, respectively, in current portion of lease liabilities and lease liabilities long-term on the condensed consolidated balance sheet.

Total operating lease costs were approximately $151,000 and $76,000 for the three months ended June 30, 2021 and June 30, 2020, respectively, and $286,000 and $152,000 for the six months ended June 30, 2021 and June 30, 2020, 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 $114,000 and $110,000 for the three months ended June 30, 2021 and June 30, 2020, respectively, and $226,000 and $238,000 for the six months ended June 30, 2021 and June 30, 2020, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. Further, at June 30, 2021, operating leases had a weighted average remaining lease term of 1.06 years.

As of June 30, 2021, future minimum lease payments under the Company's operating leases are as follows:

Remainder of 2021	$	236,000
2022		277,000
Total future minimum lease payments		513,000
Less: accreted interest		21,000
Total operating lease liabilities	$	492,000

7. COMMITMENTS AND CONTINGENCIES

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 $45.5 million to the former stockholders of MBI contingent upon the achievement of specified funding, product development and regulatory milestones. On June 30, 2021, a total of $1.25 million of that potential 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 recorded on the Company's consolidated balance sheets in accrued expenses. See also Note 10.

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 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, to support the development of Ovaprene and DARE-FRT1. 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 statement of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

Ovaprene

Since 2018, the Company has received approximately $1.9 million of non-dilutive grant funding from NICHD for clinical development efforts supporting Ovaprene. The final notice of award the Company received was for approximately $731,000 in April 2020, all of which has been funded to date.

The Company recorded credits to research and development expense for costs related to the NICHD award of an immaterial amount during both the three and six months ended June 30, 2021 and approximately $167,000 and $459,000 during the three and six months ended June 30, 2020, respectively.

DARE-FRT1

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

The Company recorded credits to research and development expense for costs related to the NICHD award of approximately $12,000 and $26,000 during the three and six months ended June 30, 2021, respectively. At June 30, 2021, the Company recorded a receivable of approximately $12,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

DARE-LARC1 Non-Dilutive Grant Funding

MBI Grant Agreement

The Company's wholly-owned subsidiary, MBI, has an agreement with the Bill & Melinda Gates Foundation, or the Foundation, under which the Company was awarded $5.4 million to support the development of DARE-LARC1. 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 payments under this agreement of approximately $2.9 million in 2019 and $2.5 million in 2020. 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. There is no deferred grant funding liability under this agreement recorded in the Company's condensed consolidated balance sheet at June 30, 2021.

2021 DARE-LARC1 Grant Agreement

On June 30, 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. An initial payment of $11.45 million was due to the Company in July 2021 (see Note 10). Additional payments are contingent upon the DARE-LARC1 program’s achievement of specified development and reporting milestones. At June 30, 2021, no payments had been received under the 2021 DARE-LARC1 Grant Agreement, and no deferred grant funding liability under this agreement was recorded in the Company's condensed consolidated balance sheet.

9. NET LOSS PER SHARE

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under outstanding options and warrants to purchase shares of the Company’s common stock. Common share equivalents are excluded from the diluted net loss per share calculation if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted net loss per common share for the period indicated because of their anti-dilutive effect:

Potentially dilutive securities	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	4,656,666	2,766,626	4,656,666	2,766,626
Warrants	1,856,143	2,034,643	1,856,143	2,034,643
Total	6,512,809	4,801,269	6,512,809	4,801,269

10. SUBSEQUENT EVENTS

Milestone Payments

As discussed in Note 3 above, under the Company's license agreements with Catalent and MilanaPharm, the Company must make certain milestone payments upon achieving certain development and commercial sales milestones. With regards to the Catalent license agreement, in August 2021, $1.0 million of milestone payments became payable upon achievement of certain development milestones. In accordance with the license agreement, the amount payable is offset by the $100,000 annual maintenance fee, for a net amount payable of $900,000. With regards to the MilanaPharm license agreement, in August 2021, $250,000 of milestone payments became payable upon achievement of certain development milestones.

CRADA with NICHD for the Pivotal Phase 3 Study of Ovaprene

On July 8, 2021, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with NICHD for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene, or the Phase 3. The Phase 3 will be conducted within NICHD's Contraceptive Clinical Trial Network with NICHD contractor Health Decisions Inc., a contract research organization, providing clinical coordination and data collection and management services for the Phase 3. The Company and NICHD will each provide medical oversight and final data review and analysis for the Phase 3 and will work together to prepare the final report of the results of the Phase 3. The Company is responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in payments to NICHD to be applied toward the costs of conducting the Phase 3. NICHD will be responsible for the other costs related to the conduct of the Phase 3. In July 2021, in accordance with the payment schedule under the CRADA, the Company paid $250,000 of the total amount payable to NICHD.

Milestone Payments to Former MBI Stockholders

As discussed in Note 3 and Note 7 above, in connection with the acquisition of MBI, the Company agreed to pay additional consideration of up to $45.5 million to the former stockholders of MBI contingent upon the achievement of specified funding, product development and regulatory milestones. On June 30, 2021, a total of $1.25 million of that potential additional 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. Pursuant to the terms of the merger agreement, the Company, in its sole discretion, could elect to pay the $1.25 million in milestone payments in cash, shares of the Company's common stock or a combination of both, except that $75,000 must be paid in cash to the stockholders' representative. In July 2021, the Company's board of directors elected to make these milestone payments in shares of the Company's common stock. The Company expects to issue approximately 700,000 shares of its common stock to former stockholders of MBI and pay $75,000 to the stockholders' representative in satisfaction of the $1.25 million in milestone payments associated with milestones achieved on June 30, 2021.

Exercise of February 2018 Warrants

On July 7, 2021, warrants to purchase an aggregate of 25,000 shares of common stock were exercised at an exercise price of $0.96 per share resulting in gross proceeds to the Company of approximately $24,000 (see Note 5).

Sales of Common Stock

Between July 1, 2021 and August 9, 2021, the Company sold an aggregate of approximately 13.1 million shares of common stock under its ATM equity offering program for aggregate net proceeds of approximately $25.4 million.

Receipt of Payment under 2021 DARE-LARC1 Grant Agreement

In July 2021, the Company received an initial payment of $11.45 million under the 2021 DARE-LARC1 Grant Agreement (see Note 8). The Company's receipt of any additional funding is contingent upon the DARE-LARC1 program's achievement of development and reporting milestones specified in the 2021 DARE-LARC1 Grant Agreement.

FDA Accepts for Filing the Company's NDA for DARE-BV1 and Grants Waiver of Application Fee

In July 2021, the Company was notified that the FDA granted the Company's small business waiver and refund request with respect to the $2.9 million application fee the Company paid in June 2021 upon the submission of its new drug application, or NDA, for DARE-BV1 for the treatment of bacterial vaginosis. The Company expects to receive the refund in the third quarter of 2021. The $2.9 million application fee refund is recorded in other receivables on the Company's condensed consolidated balance sheets at June 30, 2021.

In August, 2021, the Company announced that the FDA accepted for filing and granted Priority Review for the Company's NDA for DARE-BV1 for the treatment of bacterial vaginosis, and that the FDA set a PDUFA date of December 7, 2021 for the target completion of its review of the NDA.

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, 2020 included in our Annual Report on Form 10-K for the year ended December 31, 2020, or our 2020 10-K, filed with the Securities and Exchange Commission, or SEC, on March 30, 2021. 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 2020 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. 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 clinical-stage biopharmaceutical company committed to advancing innovative products for women's health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. Our business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid to late-stage clinical development, and to establish and leverage strategic partnerships to achieve commercialization. We and our wholly owned subsidiaries operate in one business segment.

Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through mid and late stages of clinical development or approval. Our portfolio includes three product candidates in advanced clinical development:

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis;
- **Ovaprene®**, a novel, hormone-free, monthly 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 three product candidates in Phase 1 clinical development or that we believe are Phase 1-ready:

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring, or IVR, for the treatment of menopausal symptoms, including vasomotor symptoms, as part of a hormone therapy following menopause;
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization treatment plan; and

- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy in patients with hormone-receptor positive breast cancer.

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

- **DARE-LARC1**, a contraceptive implant with a woman-centered design that has the potential to be a long-acting, convenient and user-controlled contraceptive option;
- **ADARE-204 and ADARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

Our primary operations have consisted of, and are expected to continue to consist primarily of, research and development activities to advance our portfolio of product candidates through clinical development and regulatory approval. We have focused on the advancement of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%, and plan to continue to focus our resources on these product candidates for the remainder of 2021 and in 2022. In addition, while we expect to incur significant research and development expenses for the DARE-LARC1 program each year for the next several years, we expect all such expenses will be supported by the non-dilutive grant funding discussed below.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any revenue. We are subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key 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, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, and product liability.

The effect of the COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain an evolving and uncertain risk to our business, operating results, financial condition and stock price. Challenges to vaccination efforts, variants of the virus that causes COVID-19 circulating globally, including within the U.S., and other causes of virus spread have resulted in, and may continue to result in, local, state, federal and foreign governments to reimpose restrictions in various geographies. To date, neither government-imposed restrictions or other governmental actions nor our remote working arrangements or those of our third-party service providers and contract manufacturers have materially affected our ability to operate our business, and we have been able to advance our portfolio of product candidates in meaningful ways during the pandemic, including by commencing and completing a Phase 3 clinical trial of DARE-BV1 during 2020. However, the effects of the pandemic could have a material adverse impact on our business, operating results and financial condition, including, without limitation, by increasing the anticipated aggregate costs and timelines for the development and marketing approval of our product candidates. For example, the pace of enrollment of participants in our ongoing clinical trial for Sildenafil Cream, 3.6% at certain sites has recently declined because of those sites adhering to governmental guidelines recommending reductions or changes in their operations intended to reduce the spread of COVID-19. The commencement and/or completion of clinical trials for our product candidates, including Ovaprene, could also be delayed for similar reasons or because of individuals being less inclined to participate in or complete trials that require multiple clinic visits as a result of increased transmissibility of the virus that causes COVID-19 or due to a spike in hospitalizations in the U.S. that causes healthcare industry resources to be diverted from participating in research and development activities for investigational products unrelated to COVID-19 or because the operations of contract manufacturers of clinical supplies are disrupted due to the effects of COVID-19 and are unable to fulfill the our needs. Conversely, continued re-opening of the U.S. and global economies may delay enrollment in clinical trials for Sildenafil Cream, 3.6% and Ovaprene as individuals gain more freedom to travel and participate in other activities that have not been available to them since the beginning of the pandemic and may be less inclined to participate in or complete studies that require multiple clinic visits. In addition, the effects of the pandemic could adversely impact the our ability to raise capital when needed or on terms favorable or acceptable to us. Continued uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, workplace environments and capital markets, preclude any prediction as to the ultimate effect of the pandemic on our business. See also the risk factor titled, *The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs,* in Part II, Item 1A, Risk Factors of this report.

Clinical Stage Product Candidates

DARE-BV1

In August 2021, the FDA accepted for filing our new drug application, or NDA, for DARE-BV1 for the treatment of bacterial vaginosis and granted our request for Priority Review. The DARE-BV1 NDA is supported by positive data from our DARE-BVFREE Phase 3 clinical trial of DARE-BV1. In December 2020, we announced that the DARE-BVFREE study met its primary endpoint, demonstrating that a single administration of DARE-BV1 was superior to placebo as a primary therapeutic intervention for women diagnosed with bacterial vaginosis. The FDA grants Priority Review to NDAs for potential therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. A Priority Review designation means the FDA's goal is to take action on the NDA within six months of its receipt of the NDA submission, compared to 10 months under a standard review. We submitted the DARE-BV1 NDA to the FDA in June 2021, along with the application fee due under the Prescription Drug User Fee Act, or PDUFA. In July 2021, we were notified that the FDA granted our small business waiver and refund request for the application fee, and we expect to receive the refund in the third quarter of 2021. The PDUFA target action date for the DARE-BV1 NDA is December 7, 2021. If the FDA approves the NDA in 2021, we would expect a commercial launch of DARE-BV1 in the United States in the first half of 2022. Ongoing strategic discussions and other activities to support a robust market introduction of the product in 2022, if approved, are underway, and we intend to finalize and announce the commercialization strategy for DARE-BV1 in the U.S. this year. Commercialization arrangements for DARE-BV1 may include granting pharmaceutical companies with other commercial products in women's health out-licenses to exclusively market, sell and distribute the product, if approved, in specific geographies, engaging commercial sales organizations to utilize their internal sales organizations and other commercial functions for market access, marketing, distribution, and other related services, or assembling a hybrid of these potential options to co-promote the product.

Ovaprene

Based on the positive results of our postcoital test (PCT) clinical trial of Ovaprene, and with the support of Bayer under the commercial license agreement we executed in January 2020, we are conducting activities to support submission of an Investigational Device Exemption application, or IDE, to the FDA in the fourth quarter of 2021 for a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene. We are designing the Phase 3 study to evaluate the safety and efficacy of Ovaprene to prevent pregnancy when used over a period of at least six months and up to approximately 12 months by approximately 250 women and will seek to confirm alignment with the FDA on the study design prior to commencement. We anticipate commencement of the Phase 3 study in 2022. In July 2021, we 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 the NICHD, part of the National Institutes of Health, for the conduct of the Phase 3 study, which will be conducted within NICHD's Contraceptive Clinical Trial Network with NICHD contractor Health Decisions Inc., a contract research organization, providing clinical coordination and data collection and management services for the Phase 3 study. 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 in payments to NICHD to be applied toward the costs of conducting the Phase 3 study. 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 Health Decisions Inc., the clinical sites, and other parties involved with the study. If the planned Phase 3 study is successful, we expect the data to support a pre-market approval submission to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

Sildenafil Cream, 3.6%

In March 2021, we announced initiation of our Phase 2b RESPOND clinical trial of Sildenafil Cream, 3.6% in women with FSAD. During the Phase 2b RESPOND clinical trial, subjects will use Sildenafil Cream, 3.6% and placebo cream in their home setting and will document genital arousal symptoms and changes in distress using patient reported outcome instruments. The primary efficacy endpoint of the study is a composite endpoint that includes patient-reported improvement in genital sensations of arousal and reduction in distress associated with FSAD. The Phase 2b RESPOND trial is designed to evaluate Sildenafil Cream, 3.6% compared to placebo cream over 12 weeks of dosing following both a non-drug and placebo run-in period. The study is expected to randomize 400 to 590 subjects into the double-blind dosing period at 40 to 50 clinical sites in the U.S. to ensure a total of 300 (150:150) to 440 (220:220) subjects complete the 12-week double-blind dosing period. The final size of the study will be determined by a single interim analysis for unblinded sample size re-estimation, based on the study's adaptive design. An adaptive design implemented in accordance with the FDA's Guidance for Industry on adaptive designs for clinical trials of drugs mitigates the risk of the study being underpowered if the true treatment effect and variability are significantly different from estimates based on published data but are still clinically meaningful. The pace of enrollment of participants in the trial at certain sites has recently declined because of those sites adhering to governmental guidelines recommending reductions or changes in their operations intended to reduce the spread of COVID-19. Due to the potential impact on the pace of overall enrollment for the trial resulting from governmental recommendations or orders intended to reduce the spread of COVID-19 or from other effects related to COVID-19, we cannot predict with reasonable certainty at this time when the interim analysis will be conducted or when we will report topline data from the trial. We anticipate that the aggregate costs of the Phase 2b RESPOND clinical trial of Sildenafil Cream, 3.6% will be between approximately $15.0 to $17.0 million, not all of which will be payable in fiscal 2021.

DARE-HRT1

In June 2021, we announced positive topline results from our Phase 1 clinical trial of DARE-HRT1. DARE-HRT1 is a novel intravaginal ring, or IVR, designed to deliver bio-identical 17β-estradiol and bio-identical progesterone continuously over a 28-day period as part of a hormone therapy regimen to treat the vasomotor symptoms, or VMS, and genitourinary syndrome associated with menopause. The randomized, open label, three-arm, parallel group Phase 1 evaluated the pharmacokinetics, or PK, and safety of DARE-HRT1 in approximately 30 healthy, post-menopausal women with intact uteri, and was conducted by our wholly owned Australian subsidiary at specialty women's health sites in Australia. The primary objective of the study was to describe the PK parameters of two different dose combinations (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) over 28 days. Secondary endpoints of the study were to assess the safety and tolerability of DARE-HRT1 and to compare the systemic exposure of estradiol, estrone, and progesterone of DARE-HRT1 over 28 days against a daily combination of oral estrogen (Estrofem®) and oral progesterone (Prometrium®). Data from the study demonstrate that DARE-HRT1 successfully delivered estradiol and the progesterone over the 28-day evaluation period. The levels of estradiol released from both the lower and higher dose formulations of DARE-HRT1 evaluated in the study achieved or exceeded the levels that were targeted for hormone therapy. Target levels of estradiol for hormone treatment for either the VMS or vaginal symptoms of menopause were established by reviewing PK levels published for FDA-approved products for both the treatment of VMS as well as the genitourinary symptoms of menopause. Based on the estradiol PK data in the Phase 1 study, the results support further development of DARE-HRT1 as a potentially effective hormone therapy for both VMS and vaginal symptoms associated with menopause. The levels of progesterone released from both versions of DARE-HRT1 evaluated in the study met the objectives of releasing progesterone. Progesterone is used in hormone therapy to reduce the impact of estrogen on nontarget sites, such as the endometrium, to prevent estrogen-induced endometrial hyperplasia. The study treatment was well tolerated with the most common adverse events consistent with other vaginal products. There was one early discontinuation due to an adverse event, which was found to be unrelated to study treatment or participation, and no serious adverse events were reported. The proportion of participants reporting adverse events was similar across all dose groups, the two DARE-HRT1 groups as well as the group receiving the daily combination of FDA-approved oral estrogen and oral progesterone products, with 89% of adverse events mild in severity and all other adverse events (11%) rated as moderate. DARE-HRT1 also had a high level of acceptability in the study, with over 80% of subjects on the lower and higher dose versions of DARE-HRT1 reporting the IVR as comfortable or very comfortable. Over 80% of subjects in each IVR dose group stated they were either somewhat or very likely to use the IVR for a women’s health condition or disease if needed. Following clinical development, we intend to leverage the existing safety and efficacy data on the active ingredients in DARE-HRT1, estradiol and progesterone, to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-HRT1 in the U.S.

DARE-VVA1

We plan to initiate a randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging Phase 1 clinical study of DARE-VVA1 in 2021 to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of DARE-VVA1. The study will be conducted by our wholly owned Australian subsidiary at specialty women's health sites in Australia. DARE-VVA1 is a proprietary formulation of tamoxifen for vaginal administration that we are developing as a hormone-free treatment for vulvar and vaginal atrophy, or VVA, in a hormone-receptor positive, breast cancer patient population. We expect the study will enroll approximately 40 postmenopausal women with VVA, including women with a history of hormone-receptor positive breast cancer, at approximately three study sites.

Our currently anticipated timelines and aggregate costs for the development of our product candidates could be delayed and could increase as a result of the COVID-19 pandemic. See the risk factor titled, *The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs,* in Part II, Item 1A, Risk Factors of this report.

Recent Events

FDA Acceptance of NDA, Waiver of Application Fee, and Approval of Refund Request for DARE-BV1

On August 9, 2021, we announced that the FDA accepted for filing and granted Priority Review for our NDA for DARE-BV1 for the treatment of bacterial vaginosis, and that the FDA set a PDUFA date of December 7, 2021 for the target completion of its review of the NDA.

In July 2021, we were notified that the FDA granted our small business waiver and refund request with respect to the $2.9 million application fee we paid in June 2021 upon the submission of our NDA for DARE-BV1. We expect to receive the refund in the third quarter of 2021. The $2.9 million application fee refund is recorded in other receivables on our condensed consolidated balance sheets at June 30, 2021.

CRADA with NICHD for Pivotal Phase 3 Study of Ovaprene

On July 8, 2021, we entered into a CRADA with NICHD for the conduct of our planned pivotal Phase 3 clinical study of Ovaprene. See above under the subheading “Clinical Stage Product Candidates – Ovaprene.” Pursuant to the terms of the CRADA, we are responsible for providing a total of $5.5 million in four payments to NICHD to be applied toward the costs of conducting the Phase 3 study, $250,000 of which we paid in July 2021, and $1.25 million of which is due in the fourth quarter of 2021. Payment 3, due in the first quarter of 2022, is $3.5 million, and Payment 4, due in the second quarter of 2023, is $500,000. 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 other parties involved with the study. Either we or NICHD may terminate the CRADA for any reason upon 30 days’ prior written notice to the other party. If the CRADA is terminated before completion of the Phase 3 study, NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study. If we terminate the CRADA before the completion of any active study protocol, we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the study. NICHD may retain and use payments we make under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination, and any unused funds will be returned to us. Under the CRADA, each party granted the other party rights to use their respective background inventions solely to the extent necessary to conduct the activities described in the research plan in the CRADA. Subject to the U.S. government’s nonexclusive, nontransferable, irrevocable, paid-up right to practice any CRADA invention for research or other government purposes, each party will own inventions, data and materials produced by its employees, and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed. The CRADA also contains customary representations, warranties, and indemnification and confidentiality obligations. The CRADA expires five years from its effective date.

DARE-LARC1 Non-Dilutive Grant Funding

On June 30, 2021, we entered into an agreement with the Bill & Melinda Gates Foundation, or the Foundation, under which we were awarded a new grant of up to $48.95 million to support the 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. We received an initial payment of $11.45 million in July 2021. Additional payments under the agreement are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones. Under the agreement, we agreed to make DARE-LARC1, and any other products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the project funded by the grant (referred to as Funded Developments), available and accessible at an affordable price to people most in need within developing countries, and to promptly and broadly disseminate the knowledge and information gained from the project funded by the grant (referred to as the Global Access Commitment). In connection with the Global Access Commitment, under the agreement, we also granted the Foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and essential background technology, or the Humanitarian License. We are required to ensure that the Humanitarian License survives the assignment or transfer of Funded Developments and essential background technology. If we demonstrate to the satisfaction of the Foundation that the global access contemplated by the Global Access Commitment can best be achieved without the Humanitarian License, we and the Foundation will make good faith efforts to modify or terminate the Humanitarian License, as appropriate. Any funds we receive under this agreement, and any interest or other income generated thereby, that are not used for, or committed to, the development of DARE-LARC1 in accordance with the agreement upon the expiration or termination of the agreement must be returned promptly to the Foundation.

Milestone Payments to Former MBI Stockholders

In connection with our acquisition of Dare MB Inc. (formerly, Microchips Biotech, Inc.), or MBI, in 2019, we issued an aggregate of approximately 3.0 million shares of our common stock to the holders of MBI's capital stock outstanding immediately prior to the effective time of the merger and we agreed to pay them additional consideration of up to $46.5 million contingent upon the achievement of specified funding, product development and regulatory milestones. On June 30, 2021, a total of $1.25 million of that potential additional consideration became payable upon the achievement of certain of the funding and product development milestone events. Pursuant to the terms of the merger agreement with MBI, we have sole discretion to elect to pay the $1.25 million in milestone payments in cash, shares of our common stock or a combination of both, except that $75,000 must be paid in cash to the stockholders' representative. In July 2021, our board of directors elected to make these milestone payments in shares of our common stock. We expect to issue approximately 700,000 shares of our common stock to former stockholders of MBI and pay $75,000 to the stockholders' representative in satisfaction of the $1.25 million in milestone payments associated with milestone events achieved in June 2021.

Positive Results of DARE-HRT1 Phase 1 Clinical Study

On June 28, 2021, we announced positive topline results from our Phase 1 clinical trial of DARE-HRT1. See above under the subheading "Clinical Stage Product Candidates – DARE-HRT1."

2021 ATM Sales Agreement

On April 7, 2021, we entered into a sales agreement with SVB Leerink LLC to sell shares of our common stock from time to time through an “at-the-market,” or ATM, equity offering program under which SVB Leerink would act as our agent. Under the sales agreement, we set the parameters for the sale of shares of our common stock, including the maximum number or amount of shares to be sold, the time period during which sales may be made, any limitation on the number or amount of shares that may be sold in any one trading day, and any minimum price below which sales may not be made. Subject to the terms and conditions of the sales agreement, the sales agent could sell shares of our common stock by any method permitted by law deemed to be an "at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including, without limitation, including sales made directly on or through the Nasdaq Capital Market, on or through any other existing trading market for our common stock or to or through a market maker. The sales agent must use commercially reasonable efforts in conducting such sales activities consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and applicable Nasdaq rules. If expressly authorized by us, the sales agent could also sell shares in privately negotiated transactions. We made certain customary representations, warranties and covenants to the sales agent in the sales agreement, and we agreed to customary indemnification and contribution obligations, including with respect to liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended, or the Exchange Act. The sales agreement may be terminated by us for any or no reason at any time upon five days' prior notice to the sales agent or by the sales agent for any or no reason at any time upon five days' prior notice to us. Under the sales agreement, we may issue and sell up to $50.0 million of shares of our common stock. We have no obligation to sell any shares under the sales agreement, and we may suspend solicitation and offers under the sales agreement for any reason in our sole discretion. We agreed to pay the sales agent a commission equal to 3.0% of the gross proceeds from the sales of shares pursuant to the Sales Agreement. Shares of our common stock sold under the sales agreement have been and will be issued pursuant to our 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 by the SEC on April 7, 2021, and the prospectus supplement, dated April 7, 2021, relating to the offering.

Financial Operations Overview

Revenue

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

Research and Development Expenses

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

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

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

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

License Fees

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

General and Administrative Expense

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

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 1 to our financial statements contained in our 2020 10-K, and Note 2 to our unaudited condensed consolidated financial statements contained in this report.

Results of Operations

Comparison of Three Months Ended June 30, 2021 and 2020 (Unaudited)

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

	Three Months Ended June 30,		Change
	2021	2020	$
Operating expenses:			
General and administrative	$ 1,797,637	$ 1,557,548	$ 240,089
Research and development	7,340,289	5,547,450	1,792,839
License fees	25,000	20,833	4,167
Total operating expenses	9,162,926	7,125,831	2,037,095
Loss from operations	(9,162,926)	(7,125,831)	(2,037,095)
Other income	175	1,618	(1,443)
Net loss	$ (9,162,751)	$ (7,124,213)	$ (2,038,538)
Other comprehensive loss:			
Foreign currency translation adjustments	(8,880)	12,090	(20,970)
Comprehensive loss	$ (9,171,631)	$ (7,112,123)	$ (2,059,508)

Revenues

We did not recognize any revenues for either of the three months ended June 30, 2021 or 2020.

General and administrative expenses

The increase of $240,089 in general and administrative expenses for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020 was primarily attributable to increases in personnel costs of approximately $179,000, in stock-based compensation expense of approximately $149,000 and in professional services expense of approximately $24,000, partially offset by decreases in facilities and office expenses of approximately $115,000.

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

Research and development expenses

The increase of approximately $1.8 million in research and development expenses for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020 was primarily attributable to increases in costs related to development activities of approximately: (a) $1.9 million related to our lead clinical-stage product candidates, primarily driven by the Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene, and (b) $846,000 related to development activities for our Phase 1 and Phase 1-ready programs, offset by a decrease in development costs of $1.1 million as a result of the completion of the DARE-BV1 Phase 3 clinical trial in December 2020.

As previously reported, we expect research and development expenses to increase significantly in 2021 as we continue to develop our product candidates and seek FDA approval for DARE-BV1, and we expect our research and development spend to vary across our fiscal quarters and that our research and development spend during the second half of 2021 will be greater than the spend in the first half. If we advance our programs as currently planned, our research and development expenses for 2021 could be more than double our research and development expenses for 2020. Research and development expenses for the first half of 2021 included $250,000 in milestone payments under our license agreements related to certain of our product candidates paid by us to our third-party licensors. Research and development expenses for the second half of 2021 may include up to an additional $1.3 million in milestone payments under license agreements related to certain of our product candidates payable by us to our third-party licensors, including the $1.0 million payable with respect to the milestone achieved in August 2021 under our Catalent license agreement ($100,000 of which will be offset by the annual license fee) and the $250,000 payable with respect to the milestone achieved in August 2021 under our MilanaPharm license agreement. The pace and extent of our research and development activities and, therefore, our research and development spend, will depend on our cash resources. In regard to Sildenafil Cream, 3.6%, we anticipate that the costs of the planned Phase 2b clinical study will be approximately $15.0 to $17.0 million, not all of which will be payable in 2021.

License fees

For the three months ended June 30, 2021 we accrued $25,000 of the $100,000 annual license maintenance fee payable in the second quarter of 2021 under our license agreement related to DARE-HRT1.

For the three months ended June 30, 2020 we accrued $20,833 of the $50,000 license maintenance fee payable in the second quarter of 2020 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 decrease of $1,443 in other income for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020 was primarily due to a decrease in interest earned on cash balances in the current period.

Comparison of Six Months Ended June 30, 2021 and 2020 (Unaudited)

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

	Six Months Ended June 30,		Change
	2021	2020	$
Operating expenses:			
General and administrative	$ 3,737,965	$ 3,419,313	$ 318,652
Research and development	13,068,495	7,927,254	5,141,241
License fees	50,000	33,333	16,667
Total operating expenses	16,856,460	11,379,900	5,476,560
Loss from operations	(16,856,460)	(11,379,900)	(5,476,560)
Other income	178	3,439	(3,261)
Gain on extinguishment of note payable	369,887	—	369,887
Net loss	$ (16,486,395)	$ (11,376,461)	$ (5,109,934)
Other comprehensive loss:			
Foreign currency translation adjustments	(15,721)	(10,854)	(4,867)
Comprehensive loss	$ (16,502,116)	$ (11,387,315)	$ (5,114,801)

Revenues

We did not recognize any revenues for either of the six months ended June 30, 2021 or 2020.

General and administrative expenses

The increase of $318,652 in general and administrative expenses for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020 was primarily attributable to increases in personnel costs of approximately $363,000 and in stock-based compensation expense of approximately $285,000, partially offset by decreases in professional services expense of approximately $228,000 and in facilities and office expenses of approximately $88,000.

Research and development expenses

The increase of approximately $5.1 million in research and development expenses for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020 was primarily attributable to increases in costs related to development activities of approximately (a) $3.7 million related to our lead clinical-stage product candidates, primarily driven by the Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene, and (b) $1.9 million related to our Phase 1 and Phase 1-ready programs, offset by a decrease in development costs of $881,000 as a result of the completion of the DARE-BV1 Phase 3 clinical trial in December 2020.

License fees

For the six months ended June 30, 2021 we accrued $50,000 of the $100,000 annual license maintenance fee payable in the second quarter of 2021 under our license agreement related to DARE-HRT1.

For the six months ended June 30, 2020 we accrued $33,333 of the $50,000 license maintenance fee payable in the second quarter of 2020 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 and gain on extinguishment of note payable

The decrease of $3,261 in other income for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020 was primarily due to a decrease in interest earned on cash balances in the current period.

In January 2021, we were notified that the principal balance of our PPP loan and all accrued interest, which together totaled $369,887, was fully forgiven by the SBA. We recorded a gain on extinguishment of note payable and debt forgiveness income with respect to such loan forgiveness in the first quarter of 2021.

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 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 June 30, 2021, our accumulated deficit was approximately $87.9 million, our cash and cash equivalents were approximately $9.1 million, and our working capital was approximately $8.1 million. We incurred a loss from operations of approximately $16.5 million, and had negative cash flow from operations of approximately $20.2 million during the six months ended June 30, 2021.

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

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

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

Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. Historically, the cash used to fund our operations has come from a variety of sources. During the six months ended June 30, 2021, we received approximately $17.7 million of net proceeds from the sales of approximately 11.0 million shares of our common stock under our ATM sales agreements, approximately $6.8 million of net proceeds from the sales of 4.8 million shares of our common stock under our equity line, and approximately $50,400 upon the exercise of warrants. Subsequent to June 30, 2021 and through August 9, 2021, we received approximately $25.4 million of net proceeds from sales of approximately 13.1 million shares of our common stock under our ATM sales agreement, and $11.45 million in non-dilutive grant funding to advance DARE-LARC1 in non-clinical proof of principle studies. See "—Recent Events," above.

We will need to raise substantial additional capital to continue to fund our operations and to successfully execute our current operating plan, including the development of our product candidates. We will continue to seek to raise capital through the sale of shares of our common stock under our ATM sales agreement, however, when we can effect such sales and the amount of shares we can sell depends on a variety of factors to be determined by us from time to time, 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. We are also currently evaluating a variety of capital raising options, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover our operating expenses, including the development and, if approved, commercialization of our product candidates and future product candidates we may license or otherwise acquire. The amount and timing of our capital needs have been and will continue to depend highly on many factors, including the product development programs we choose to pursue and the pace and results of our clinical development efforts. If we raise capital through collaborations, strategic alliances or other similar types of arrangements, we may have to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates we would otherwise seek to develop or commercialize.

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders. 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.

Cash Flows

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

	Six months ended June 30,	
	2021	**2020**
Net cash used in operating activities	$ (20,168,469)	$ (10,684,464)
Net cash used in investing activities	—	(15,246)
Net cash provided by financing activities	24,626,464	11,277,329
Effect of exchange rate changes on cash and cash equivalents	(15,721)	(10,854)
Net increase in cash and cash equivalents	$ 4,442,274	$ 566,765

Net cash used in operating activities

Cash used in operating activities for the six months ended June 30, 2021 included the net loss of $16.5 million, decreased by non-cash stock-based compensation expense of approximately $771,000 and increased by the non-cash gain on extinguishment of the note payable and accrued interest of approximately $370,000 related to our PPP loan. A component providing operating cash was an increase in accrued expenses of approximately $1.0 million. Components reducing operating cash were an increase in other receivables of approximately $2.5 million related to the PDUFA application fee paid in June 2021, which we expect to be refunded in the third quarter of 2021, a decrease in deferred grant funding of approximately $1.6 million, a decrease in accounts payable of approximately $805,000 and an increase in prepaid expenses of approximately $138,000.

Cash used in operating activities for the six months ended June 30, 2020 included the net loss of $11.4 million, decreased by non-cash stock-based compensation expense of approximately $348,000. Components providing operating cash were an increase of approximately $631,000 in accounts payable, an increase of approximately $1.0 million in deferred license revenue and a decrease in other receivables of approximately $378,000. Components reducing operating cash were a $1.1 million increase in prepaid expenses, a decrease in accrued expenses of approximately $458,000 and a decrease in deferred grant funding of approximately $75,000.

Net cash provided by financing activities

Cash provided by financing activities for the six months ended June 30, 2021 and 2020 consisted of approximately $24.6 million and $11.3 million in the aggregate, respectively, primarily from sales of our common stock under our ATM sales agreement and our equity line during the current year period, and primarily from sales of shares of our common stock under our ATM sales agreement and upon the exercise of warrants, and from the proceeds related to the loan we received under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act during the prior period.

Net cash used in investing activities

No cash was provided by or used in investing activities for the six months ended June 30, 2021. Cash used in investing activities for the six months ended June 30, 2020 was $15,246.

License and Royalty Agreements

We have committed to make various royalty and milestone payments under the product license and development agreements related to DARE-BV1, Ovaprene, and Sildenafil Cream, 3.6%, and under the 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.

At the conclusion of the quarterly period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of June 30, 2021 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 of 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 2020 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 2020 10-K other than as described below.

Risks Related to Our Business

If the FDA issues a complete response letter following its review of our DARE-BV1 NDA, our stock price could drop immediately and significantly and our ability to raise additional capital to continue our operations and execute our current product development plans may be materially adversely affected.

In August 2021, we were notified that the FDA accepted our NDA for DARE-BV1 for filing. Accordingly, the FDA is conducting a substantive review of the NDA to determine whether to approve DARE-BV1 for the treatment of bacterial vaginosis or whether they need additional information to make a decision. After evaluating the NDA and all related information, including inspection reports regarding the manufacturing facilities where the drug product or its active pharmaceutical ingredient, or API, will be produced and the DARE-BVFREE clinical trial sites, the FDA will either issue an approval letter or a complete response letter, or CRL, that describes all of the specific deficiencies in the NDA identified by the agency. An approval letter would authorize commercial marketing of DARE-BV1 in the U.S. with specific prescribing information. A CRL would indicate that the review cycle of the NDA is complete and the NDA will not be approved in its present form. The deficiencies identified in a CRL may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. If a CRL is issued for the NDA and the deficiencies identified therein are major, the timeline to develop DARE-BV1 could become significantly longer than anticipated and the associated costs significantly greater, in which case we may determine that continuing to pursue development and regulatory approval of DARE-BV1 would not be in the best interests of our company and stockholders. If a CRL is issued for the NDA, even if the deficiencies identified therein are minor, there may be an immediate and significant decrease in the market price of our common stock, our reputation could suffer, we may become subject to class action securities lawsuits (regardless of their merit), and our ability to raise additional capital to fund our operations and the continued development of our product candidates could be significantly harmed, the occurrence of any of which could have a material adverse effect on our business, results of operations and financial condition.

The FDA does not always meet its PDUFA goal dates, and even with Priority Review, the FDA's review of the DARE-BV1 NDA could be very lengthy, and as a result, even if the NDA is ultimately approved, commercial launch of DARE-BV1 in the U.S. may not occur in the timeframe we currently anticipate.

The FDA granted Priority Review to the DARE-BV1 NDA and set a PDUFA target action date of December 7, 2021. However, the FDA does not always meet its PDUFA goal dates, and the review process may be prolonged by FDA requests for additional information or clarification regarding information in the NDA, and the timing of our response to any such inquiry. The review process for the DARE-BV1 NDA may extend past December 7, 2021 and could be very lengthy, which would delay commercial launch of DARE-BV1 in the U.S. beyond our currently anticipated timeframe and could have a material adverse effect on our business, results of operations and financial condition. Delays in the FDA's review of the DARE-BV1 NDA could also cause the market price of our common stock to decline.

We have not finalized our commercial strategy for DARE-BV1 and currently do not have a commercial partner or the internal capabilities to market, distribute or sell DARE-BV1 should the NDA receive FDA approval, and we may not successfully establish such arrangements or capabilities on a timely basis, or at all.

Because antibiotics are commonly used to treat bacterial infections and vaginal administration of a drug product for vaginal bacterial infections is common and preferable to some women and healthcare providers, and because the API of DARE-BV1 is familiar to U.S. clinicians as an antibiotic with FDA approval in other formulations to treat bacterial infections, including bacterial vaginosis, we believe the commercial launch strategy for DARE-BV1 in the U.S. is relatively straightforward, and we expect to finalize our commercialization strategy and establish a commercial partner for DARE-BV1 before the end of 2021 to enable commercial launch of the product in the U.S., if approved, in the first half of 2022. However, we currently do not have a commercial partner or the necessary infrastructure to market, distribute and sell DARE-BV1 without a partner. We may not be successful in attracting an acceptable commercial partner or entering into an agreement with acceptable terms on a timely basis, or at all, which could significantly delay commercial launch of DARE-BV1, if approved, and adversely impact the potential for commercial success of the product.

Our arrangements for commercialization of DARE-BV1 may include granting pharmaceutical companies with other commercial products in women's health out-licenses to exclusively market, sell and distribute the product, if approved, in specific geographies, engaging commercial sales organizations to utilize their internal sales organizations and other commercial functions for market access, marketing, distribution, and other related services, or assembling a hybrid of these potential options to co-promote the product. In light of the high penetration of generic products and the recent commercial underperformance of branded products for the treatment of bacterial vaginosis, an agreement with a third party granting rights to exclusively market, sell and distribute DARE-BV1 in the U.S. may provide only modest near-term payments to us, with a significantly greater proportion of the value entirely dependent upon achievement of future sales milestones and the amount of net sales. Partnering with a commercial sales organization would allow us to retain greater control and greater value from sales revenue, but it would require rapid and significant changes to our organization to develop, implement and maintain the infrastructure necessary to support commercialization, as well as require significant additional capital. Any future commercial collaboration may not be successful, in which case the commercial launch of DARE-BV1, if approved, could be delayed, our ability to compete effectively against other approved treatments for bacterial vaginosis and to realize the full market potential of the product could be harmed, and our business, results of operations and financial condition could suffer.

If we fail to meet our payment obligations under the CRADA or NICHD unilaterally terminates the CRADA, the commencement, conduct and/or completion of the pivotal Phase 3 clinical study of Ovaprene could be significantly delayed.

Though the CRADA has a five-year term, either party may terminate it for any reason or for no reason upon 30 days' prior written notice to the other party. If the CRADA is terminated before completion of the Phase 3 study of Ovaprene, NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study. However, termination of the CRADA by NICHD could significantly delay the commencement, conduct and/or completion of the study and significantly increase the overall timeline and costs for development of Ovaprene. In addition, if we fail to make any scheduled payment to NICHD under the CRADA, NICHD is not obligated to carry out research and development activities until it receives the funds. Suspension by NICHD of activities under the CRADA or termination by NICHD of the CRADA could have a material adverse effect on the Phase 3 study of Ovaprene and on our business, results of operations and financial condition, and may cause the market price of our common stock to decline.

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

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

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

The COVID-19 pandemic could cause delays in current timelines for our ongoing and planned clinical studies, our regulatory submissions, potential marketing approvals and, ultimately, commercial launch of any approved product. One or more of the clinical and regulatory milestones we anticipate will occur in 2021 or 2022 may be delayed or otherwise adversely impacted as a result of the pandemic. For example, clinical trial site initiation and/or patient enrollment may be significantly delayed or suspended as a result of personnel and other resource constraints of healthcare providers, as well as adherence to governmental orders and internal policies intended to reduce the spread of COVID-19. In addition, we may experience lower than anticipated subject enrollment and completion rates, including because individuals may avoid medical settings, particularly for non-critical conditions, due to concerns of contracting COVID-19 or due to shelter-in-place and social distancing orders, or conversely, as pandemic-related restrictions ease and there are increased opportunities to travel and participate in other activities again, individuals may be less inclined to participate in or complete clinical trials such as ours that require multiple clinic visits. Commencement and completion of our clinical trials may also be significantly delayed by disruptions to production by our contract manufacturers of clinical supplies needed for those studies.

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

A key aspect of our business strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize our product candidates. As a result of the pandemic, potential and current partners may experience operational disruptions and financial and other resource constraints and implement new strategic plans that delay or reduce their efforts in the women’s health in general or in our programs in particular, which could adversely affect our ability to enter into or maintain collaborations, strategic alliances or other similar types of arrangements and may result in or contribute to disruption and delays in later-stage clinical development and, if approved, commercial launch of our product candidates.

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

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

The COVID-19 pandemic may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section and in the "Risk Factors" section of our 2020 10-K.

Risks Related to Clinical Development, Manufacturing and Commercialization

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

There are currently no FDA-approved treatments for female sexual arousal disorder, or FSAD, and there is no precedent program to reference in the design of our clinical trials for Sildenafil Cream, 3.6%. Female sexual dysfunction disorders in women vary in nature and may be the result of a variety of physiological and psychological factors. Given the variability of factors contributing to the underlying condition, clinical studies to evaluate effectiveness in any subset of the condition under the umbrella of Sexual Dysfunction, such as FSAD, are complex. While we worked with experts to develop novel patient reported outcome, or PRO, instruments for our ongoing Phase 2b study of Sildenafil Cream, 3.6%, tested the proposed PRO instruments in a content validity study, reviewed the results of that study with the FDA and aligned with the FDA on the Phase 2b study design, the Phase 2b study may nevertheless prove difficult to enroll on the anticipated timeline or fail to demonstrate effectiveness of Sildenafil Cream, 3.6% in treating FSAD. For example, Sildenafil Cream, 3.6% is designed to work primarily by increasing blood flow to the genital tissue. Therefore, it will be critical for us to identify and enroll patients in our clinical trials of Sildenafil Cream, 3.6% for whom inadequate blood flow to the genital tissue is the primary contributor to their arousal disorder. If we fail to screen properly, and instead enroll patients with different contributing factors, the results of our clinical trials are unlikely to demonstrate effectiveness of Sildenafil Cream, 3.6%. Conversely, trying to screen out patients with different contributing factors, may slow enrollment in a study, delay its completion and increase its costs. Even if we can identify and enroll a sufficient number of women for whom inadequate blood flow to the genital tissue is the primary contributing factor to their arousal disorder on the timeline we predict for a clinical study, there is no guaranty that the use of Sildenafil Cream, 3.6% will improve their general feelings of arousal or that the PRO instruments we utilize to measure the effectiveness of Sildenafil Cream, 3.6% in the study will adequately capture their genital arousal response. Given the factors contributing to arousal disorders, we may be required to run clinical trials in large patient populations, extending the timeline and increasing the cost of development for Sildenafil Cream, 3.6%. In addition, our target timeline for the Phase 2b study assumes that the final study sample size will be on the low end of the range of approximately 400 to 590 subjects and, due to the study's adaptive design, the final study sample size has not yet been determined. If the study requires a larger number of randomized subjects, enrollment may take longer than initially targeted and completion and topline data readout of the study may be delayed. Our failure to design and implement a successful clinical trial for Sildenafil Cream, 3.6% or delays in the enrollment or completion of the trial could have a material adverse effect on our business, results of operations and financial condition, as well as our stock price.

We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our product development programs. Failure of these third parties to successfully carry out their contractual duties, comply with regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our development timelines and/or failure of our programs.

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

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

In particular, as a result of the CRADA, we are highly dependent on NICHD and the third parties it engages for the commencement, conduct and completion of our pivotal Phase 3 clinical trial of Ovaprene. Pursuant to the terms of the CRADA, the study will be conducted within NICHD's Contraceptive Clinical Trial Network, or the CCTN, with NICHD contractor Health Decisions Inc. providing clinical coordination and data collection and management services for the study. NICHD is responsible for selecting participating clinical sites from the pool of CCTN sites and, together with Health Decisions Inc., overseeing the clinical investigators in the conduct of the study, providing clinical site monitoring and quality assurance along with establishing the electronic data capture database for the study and performing data analysis, which are key factors to the successful completion of a clinical trial. We do not control these third parties and, accordingly, our control over the commencement, conduct and completion of the study is limited. If NICHD or the third parties it engages for the study prioritize other projects over the study or otherwise do not devote adequate time and resources to the study, or their performance is substandard, commencement and completion of the study may be delayed or suspended or the study may be unsuccessful, any of which could significantly harm our business, operating results and financial condition, as well as our relationship with Bayer, and cause the price of our common stock to decline.

The commercial success of DARE-BV1, if approved, will depend on many factors which currently are unknown or uncertain.

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

- perceived superiority of its cure rates compared to other available treatments;
- the extent to which the approved product labeling contains features or expected benefits that differentiate it from other available treatments;
- preferences by healthcare providers and women for a vaginally administered therapy;
- the prevalence and severity of any adverse side effects;
- patient satisfaction and willingness to use it again and refer it to others;

- price pressure given today's high level of generic treatments;
- adequate coverage, pricing and reimbursement from third-party payors;
- the willingness of patients, without third-party insurance coverage or adequate reimbursement, to pay for the product;
- the capabilities of commercialization partners and their commitment of sufficient resources to market, distribute and sell the product;
- the success or failure of other branded therapies; and
- approval of new entrants, including alternative, non-antibiotic treatment options.

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

Additionally, the FDA's approval of DARE-BV1, if any, may be limited in ways which could restrict its commercial success. For example, the FDA may not allow the product labeling to include features or expected benefits that would differentiate the product from other available treatments for bacterial vaginosis, which would prevent or substantially limit advertising and promotion of those features or benefits. The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, which may adversely affect the willingness of healthcare providers to prescribe or patients to try the product. The FDA may also impose restrictions and conditions on product distribution, prescribing, or dispensing, or otherwise limit the scope of its approval, including by requiring post marketing clinical trials, sometimes referred to as "Phase 4" clinical trials, designed to further assess a product's safety and effectiveness, and/or testing and surveillance programs to monitor its safety and effectiveness.

See also "We have not finalized our commercial strategy for DARE-BV1 and currently do not have a commercial partner or the internal capabilities to market, distribute or sell DARE-BV1 should the NDA receive FDA approval, and we may not successfully establish such arrangements or capabilities on a timely basis, or at all," as well as the other risks and uncertainties related to commercialization described in the "Risk Factors" section of our 2020 10-K.

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

The grant agreement supporting the DARE-LARC1 program does not guarantee that its pre-clinical development will be successful or that we will be able to fund its clinical development in the future.

The grant agreement under which we were awarded up to $48.95 million in non-dilutive funding for pre-clinical development of DARE-LARC1 does not guarantee that its pre-clinical development will be successful or, if successful, that we will be able to fund its future clinical development. Further, while we received an initial payment of $11.45 million under the grant agreement, additional payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones during the grant period and our compliance with other obligations under the agreement, and there is no assurance those milestones will be achieved or that we will receive additional payments.

Risks Related to Our Intellectual Property

Provisions in our agreements with governmental agencies and non-profit organizations may affect our intellectual property rights.

Certain of our product development activities have been funded, are being funded and may in the future be funded, by the U.S. government and not-for-profit organizations. Our agreements for these sources of funding include, and may in the future include, terms and conditions that affect our intellectual property rights. For example, under our CRADA with NICHD for the Phase 3 clinical study of Ovaprene, the U.S. government has a nonexclusive, nontransferable, irrevocable, paid-up right to practice for research or other government purposes any invention of either party conceived or first actually reduced to practice in the party's performance of the CRADA and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed.

Under the grant agreement supporting development of DARE-LARC1, we made the Global Access Commitment and granted the Humanitarian License, and we are required to ensure that the Humanitarian License survives the assignment or transfer of Funded Developments and essential background technology. Our obligations under the Global Access Commitment and the Humanitarian License may limit the value of our rights in DARE-LARC1 and other Funded Developments.

Risks Related to Our Securities

The sale of our common stock in ATM offerings may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline.

Since 2020, we have relied on at the market, or ATM, offerings to fund a significant portion of our operations, and we may continue to use ATM offerings to fund our operations in the future. The amount of shares we sell in our ATM program is not currently limited by the "baby shelf rule;" however, if our public float is below $75 million when we file our next annual report on Form 10-K, which will be due in March of 2022, we could become subject to the baby shelf rule, meaning that our ability to conduct primary offerings under a Form S-3 registration statement could become limited by the restriction that, during any 12-month period, we may not sell securities pursuant to General Instruction I.B.6 to Form S-3 having an aggregate market value of more than one-third of our public float, calculated in accordance with the instructions to Form S-3. Sales of shares of our common stock in ATM offerings enable us to raise capital at a relatively low cost compared with other types of equity financing transactions; however, such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline.

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.	
10.1+	Grant Agreement between Daré Bioscience, Inc. and the Bill & Melinda Gates Foundation effective as of June 30, 2021					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
32.2	Certification of principal financial officer pursuant to 18 U.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

\+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

\# 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 and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Daré Bioscience, Inc.

Date: August 12, 2021

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

Date: August 12, 2021

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

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

GRANT AGREEMENT
Investment ID INV-026060
AGREEMENT SUMMARY & SIGNATURE PAGE

GRANTEE INFORMATION	
Name:	Dare Bioscience, Inc.
Tax Status:	Not exempt from federal income tax under U.S. IRC § 501(c)(3) You confirm that the above information is correct and agree to notify the Foundation immediately of any change.
Expenditure Responsibility:	This Agreement is subject to "expenditure responsibility" requirements under the U.S. Internal Revenue Code.
Mailing Address:	3655 Nobel Drive Suite 260, San Diego, California 92122, USA
Primary Contact:	Nicolas Pacelli, Vice President, Business Development, [**]

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, Washington 98102, USA
Primary Contact:	Kirsten Vogelsong, Senior Program Officer, Contraceptive Development, Integrated Development, [**]

AGREEMENT INFORMATION	
Title:	Personal Contraceptive System (DARE LARC1)
"Charitable Purpose":	To advance the development of a novel long-acting, user-controlled hormonal contraceptive implant suitable for use by women in low-resource settings
"Start Date":	Date of last signature
"End Date":	November 1, 2026
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Investment Document (date submitted [**]) • Results Framework and Tracker (date submitted [**]) • Budget (date submitted [**])

THIS AGREEMENT is between Dare Bioscience, Inc. ("Dare Bioscience", "You" or "Grantee") and the Bill & Melinda Gates Foundation ("Foundation"), and is effective as of date of last signature. Each party to this Agreement may be referred to individually as a "Party" and together as the "Parties." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

/s/ Kirsten Vogelsong

By: Kirsten Vogelsong

Title: Senior Program Officer

June 24, 2021

Date

DARE BIOSCIENCE, INC.

/s/ Sabrina Johnson

By: Sabrina Johnson

Title: CEO

June 30, 2021

Date

GRANT AGREEMENT
Investment ID INV-026060

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT
The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE
Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING
You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

ACCOUNTING FOR PERSONNEL TIME
You will track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Grant Funds. Such individuals will keep records (e.g., timesheets) of actual time worked on the Project in increments of sixty minutes or less and brief descriptions of tasks performed. You will report actual time worked consistent with those records in Your progress and final budget reports. You will submit copies of such records to the Foundation upon request.

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		[**]	$11,453,099
	[**]	[**]	[**]	Up to $[**]
	[**]	[**]		
[**]	[**]	[**]		
	[**]	[**]		
[**]	[**]	[**]		
	[**]	[**]	[**]	Up to $[**]
[**]	[**]	[**]	[**]	Up to $[**]
	[**]	[**]		
[**]	[**]	[**]		
	[**]	[**]		
[**]	[**]	[**]	[**]	Up to $[**]
[**]	[**]	[**]		
	[**]	[**]	[**]	Up to $[**]
[**]	[**]	[**]	[**]	Up to $[**]
[**]	[**]	[**]		
[**]	[**]	[**]	[**]	Up to $[**]
[**]	[**]	[**]		
	[**]	[**]		
	[**]	[**]		
[**]	[**]	[**]		
			Total Grant Amount	**Up to $48,945,928**

GRANT AGREEMENT
Investment ID INV-026060

ATTACHMENT B
TERMS & CONDITIONS

This Agreement is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE

The Foundation is awarding You this grant to carry out the project described in the Investment Document ("*Project*") in order to further the Charitable Purpose. The Foundation, in its discretion, may approve in writing any request by You to make non-material changes to the Investment Document.

MANAGEMENT OF FUNDS

USE OF FUNDS

You may not use funds provided under this Agreement *("Grant Funds")* for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date. At the Foundation's request, You will repay any portion of Grant Funds and/or Income used or committed in material breach of this Agreement, as determined by the Foundation in its discretion.

INVESTMENT OF FUNDS

You must invest Grant Funds in highly liquid investments with the primary objective of preservation of principal (e.g., interest-bearing bank accounts or a registered money market mutual fund) so that the Grant Funds are available for the Project. Together with any progress or final reports required under this Agreement, You must report the amount of any currency conversion gains (or losses) and the amount of any interest or other income generated by the Grant Funds (collectively, "*Income*"). Any Income must be used for the Project.

SEGREGATION OF FUNDS

You must maintain Grant Funds in a physically separate bank account or a separate bookkeeping account maintained as part of Your financial records and dedicated to the Project.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

HUMANITARIAN LICENSE
Subject to applicable laws and for the purpose of achieving Global Access, You grant the Foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and Essential Background Technology. “Essential Background Technology” means Background Technology that is: (a) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (b) either incorporated into a Funded Development or reasonably required to exercise the license to a Funded Development. You confirm that You have retained sufficient rights in the Funded Developments and Essential Background Technology to grant this license. You must ensure this license survives the assignment or transfer of Funded Developments or Essential Background Technology. On request, You must promptly make available the Funded Developments and Essential Background Technology to the Foundation for use solely under this license. If You demonstrate to the satisfaction of the Foundation that Global Access can best be achieved without this license, the Foundation and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION
Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. “Publication” means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, You agree to adhere to the Foundation’s Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

INTELLECTUAL PROPERTY REPORTING
During the term of this Agreement and for 5 years after, You will submit upon request annual intellectual property reports relating to the Funded Developments, Background Technology, and any related agreements using the Foundation's templates or forms, which the Foundation may modify from time to time.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS
You may not make subgrants under this Agreement. You have the exclusive right to select subcontractors to assist with the Project.

RESPONSIBILITY FOR OTHERS
You are responsible for (a) all acts and omissions of any of Your trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project, and (b) ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY

You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

POLITICAL ACTIVITY AND ADVOCACY

You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You may not use Grant Funds to support lobbying activity or to otherwise support attempts to influence local, state, federal, or foreign legislation. Your strategies and activities, and any materials produced with Grant Funds, must comply with applicable local, state, federal, or foreign lobbying law. You agree to comply with lobbying, gift, and ethics rules applicable to the Project.

OTHER

PUBLICITY

A Party may publicly disclose information about the award of this grant, including the other Party's name, the total amount awarded, and a description of the Project, provided that a Party obtains prior written approval before using the other Party's name for promotional purposes or logo for any purpose. Any public disclosure by You or Your subgrantees, subcontractors, contingent workers, agents, or affiliates must be made in accordance with the Foundation's then-current brand guidelines, which are available at: www.gatesfoundation.org/brandguidelines.

LEGAL ENTITY AND AUTHORITY

You confirm that: (a) You are an entity duly organized or formed, qualified to do business, and in good standing under the laws of the jurisdiction in which You are organized or formed; (b) You are not an individual (i.e., a natural person) or a disregarded entity (e.g., a sole proprietor or sole-owner entity) under U.S. law; (c) You have the right to enter into and fully perform this Agreement; and (d) Your performance will not violate any agreement or obligation between You and any third party. You will notify the Foundation immediately if any of this changes during the term of this Agreement.

COMPLIANCE WITH LAWS

In carrying out the Project, You will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.

COMPLIANCE WITH REQUIREMENTS
You will conduct, control, manage, and monitor the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards ("*Requirements*"). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of Your annual progress report to the Foundation, You must report whether the Project activities were conducted in compliance with all Requirements.

If the Project involves:
a. any protected information (including personally identifiable, protected health, or third-party confidential), You will not disclose this information to the Foundation without obtaining the Foundation's prior written approval and all necessary consents to disclose such information;
b. children or vulnerable subjects, You will obtain any necessary consents and approvals unique to these subjects; and/or
c. any trial involving human subjects, You will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the Foundation in reviewing documents and providing input or funding does not modify Your responsibility for determining and complying with all Requirements for the Project.

RELIANCE
You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

INDEMNIFICATION
If the Project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("*Indemnified Activities*"), You will indemnify, defend, and hold harmless the Foundation and its trustees, employees, and agents ("*Indemnified Parties*") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "*Claims*") arising out of or relating to the acts or omissions, actual or alleged, of You or Your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the Foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of Your governmental and sovereign immunities, if any.

INSURANCE
You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted industry standards and as required by law. You will ensure Your subgrantees and subcontractors maintain insurance coverage consistent with this section.

TERM AND TERMINATION

TERM
This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement. The Foundation, in its discretion, may approve in writing any request by You for a no-cost extension, including amending the End Date and adjusting any affected reporting requirements.

TERMINATION
The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS
Any Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation.

MONITORING, REVIEW, AND AUDIT
The Foundation may monitor and review Your use of the Grant Funds, performance of the Project, and compliance with this Agreement, which may include onsite visits to assess Your organization's governance, management and operations, discuss Your program and finances, and review relevant financial and other records and materials. In addition, the Foundation may conduct audits, including onsite audits, at any time during the term of this Agreement, and within four years after Grant Funds have been fully spent. Any onsite visit or audit shall be conducted at the Foundation's expense, following prior written notice, during normal business hours, and no more than once during any 12-month period.

INTERNAL OR THIRD PARTY AUDIT
If during the term of this Agreement You are audited by your internal audit department or by a third party, You will provide the audit report to the Foundation upon request, including the management letter and a detailed plan for remedying any deficiencies observed ("*Remediation Plan*"). The Remediation Plan must include (a) details of actions You will take to correct any deficiencies observed, and (b) target dates for successful completion of the actions to correct the deficiencies.

RECORD KEEPING
You will maintain complete and accurate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Grant Funds have been fully spent. At the Foundation's request, You will make such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used or committed.

SURVIVAL
A Party's obligations under this Agreement will be continuous and survive expiration or termination of this Agreement as expressly provided in this Agreement or otherwise required by law or intended by their nature.

GENERAL

ENTIRE AGREEMENT, CONFLICTS, AND AMENDMENTS

This Agreement contains the entire agreement of the Parties and supersedes all prior and contemporaneous agreements concerning its subject matter. If there is a conflict between this Agreement and the Investment Document this Agreement will prevail. Except as specifically permitted in this Agreement, no modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

NOTICES AND APPROVALS

Written notices, requests, and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the Agreement Summary & Signature Page, or as otherwise directed by the other Party.

SEVERABILITY

Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

ASSIGNMENT

You may not assign, or transfer by operation of law or court order, any of Your rights or obligations under this Agreement without the Foundation's prior written approval. This Agreement will bind and benefit any permitted successors and assigns.

COUNTERPARTS AND ELECTRONIC SIGNATURES

Except as may be prohibited by applicable law or regulation, this Agreement and any amendment may be signed in counterparts, by facsimile, PDF, or other electronic means, each of which will be deemed an original and all of which when taken together will constitute one agreement. Facsimile and electronic signatures will be binding for all purposes.

Exhibit 31.1

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2021

/s/ Sabrina Martucci Johnson

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

Exhibit 31.2

CERTIFICATIONS

I, Lisa Walters-Hoffert, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2021

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: August 12, 2021

/s/ Sabrina Martucci Johnson

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: August 12, 2021

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