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

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

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

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

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

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

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

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

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

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

As of November 8, 2021, 76,601,624 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, including a complete response letter, that it does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that it interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *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 monetize our portfolio candidates through licenses, partnerships or other types of commercialization agreements;*
- *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;*
- *Dependence on grant funding for pre-clinical development of DARE-LARC1;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results;*

- *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

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 45,570,781	$ 4,669,467
Other receivables	156,247	460,168
Prepaid expenses	2,516,126	1,854,277
Total current assets	48,243,154	6,983,912
Property and equipment, net	33,088	37,930
Other non-current assets	535,234	528,870
Total assets	$ 48,811,476	$ 7,550,712
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 605,732	$ 1,021,333
Accrued expenses	3,776,744	3,359,718
Deferred grant funding	11,156,599	1,564,553
Note payable	—	367,285
Contingent consideration	—	1,000,000
Current portion of lease liabilities	368,011	347,712
Total current liabilities	15,907,086	7,660,601
Deferred license revenue	1,000,000	1,000,000
Lease liabilities long-term	15,799	41,844
Total liabilities	16,922,885	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; 76,601,624 and 41,596,253 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	7,660	4,159
Accumulated other comprehensive loss	(170,390)	(91,388)
Additional paid-in capital	132,635,942	70,366,293
Accumulated deficit	(100,584,621)	(71,430,797)
Total stockholders' equity (deficit)	31,888,591	(1,151,733)
Total liabilities and stockholders' equity (deficit)	$ 48,811,476	$ 7,550,712

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Operating expenses				
General and administrative	$ 2,211,334	$ 1,353,069	$ 5,949,299	$ 4,772,382
Research and development	10,432,603	6,203,753	23,501,098	14,131,007
License fees	25,000	25,000	75,000	58,333
Total operating expenses	12,668,937	7,581,822	29,525,397	18,961,722
Loss from operations	(12,668,937)	(7,581,822)	(29,525,397)	(18,961,722)
Other income (expense)	1,508	(986)	1,686	2,454
Gain on extinguishment of note payable	—	—	369,887	—
Net loss	$ (12,667,429)	$ (7,582,808)	$ (29,153,824)	$ (18,959,268)
Deemed dividend from trigger of down round provision feature	—	(6,863)	—	(6,863)
Net loss to common shareholders	$ (12,667,429)	$ (7,589,671)	$ (29,153,824)	$ (18,966,131)
Foreign currency translation adjustments	(63,281)	672	(79,002)	(10,182)
Comprehensive loss	$ (12,730,710)	$ (7,588,999)	$ (29,232,826)	$ (18,976,313)
Loss per common share - basic and diluted	$ (0.18)	$ (0.24)	$ (0.45)	$ (0.69)
Weighted average number of common shares outstanding:				
Basic and diluted	70,775,508	31,588,152	64,196,162	27,381,508

See accompanying notes.

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

Nine Months Ended September 30, 2021

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

Nine Months Ended September 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**
Stock-based compensation	—	—	194,882	—	—	194,882
Issuance of common stock	4,666,798	466	5,277,156	—	—	5,277,622
Issuance cost on equity line paid in common stock	285,714	29	291,500	—	—	291,529
Issuance of common stock from the exercise of warrants	126,000	13	120,947	—	—	120,960
Deemed dividend from trigger of down round provision	—	—	6,863	—	(6,863)	—
Net loss	—	—	—	—	(7,582,808)	(7,582,808)
Foreign currency translation adjustments	—	—	—	672	—	672
Balance at September 30, 2020	**33,602,516**	**$ 3,360**	**$ 61,712,882**	**$ (112,807)**	**$ (62,989,323)**	**$ (1,385,888)**

See accompanying notes.

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

	Nine months ended September 30,	
	2021	**2020**
Operating activities:		
Net loss	$ (29,153,824)	$ (18,959,268)
Non-cash adjustments reconciling net loss to operating cash flows:		
Depreciation	19,366	36,428
Stock-based compensation	1,210,886	542,582
Non-cash operating lease cost	(69,356)	(125,517)
Non-cash loss on settlement of contingent liability	44,286	—
Gain on extinguishment of notes payable and accrued interest	(369,887)	—
Changes in operating assets and liabilities:		
Other receivables	303,921	341,650
Prepaid expenses	(661,849)	18,682
Other non-current assets	57,247	118,044
Accounts payable	(415,602)	472,124
Accrued expenses	594,629	355,395
Deferred grant funding	9,592,045	158,704
Deferred license revenue	—	1,000,000
Net cash used in operating activities	(18,848,138)	(16,041,176)
Investing activities:		
Purchases of property and equipment	(14,524)	(15,246)
Net cash used in investing activities	(14,524)	(15,246)
Financing activities:		
Net proceeds from issuance of common stock	59,588,112	14,522,645
Proceeds from the exercise of common stock warrants	254,866	1,785,980
Proceeds from the exercise of stock options	—	1
Proceeds from issuance of note payable	—	367,285
Net cash provided by financing activities	59,842,978	16,675,911
Effect of exchange rate changes on cash and cash equivalents	(79,002)	(10,182)
Net change in cash and cash equivalents	40,901,314	609,307
Cash and cash equivalents, beginning of period	4,669,467	4,780,107
Cash and cash equivalents, end of period	$ 45,570,781	$ 5,389,414
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ 308,533	$ —
Settlement of contingent closing consideration liability with stock issuance in connection with acquisition of business	$ 925,000	$ —
Milestone payment paid in common stock	$ 250,000	$ —
Issuance cost on equity paid in common stock	$ —	$ 291,428
Deemed dividend from trigger of down round provision feature	$ —	$ 6,863

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 prioritize women's health and well-being, expand treatment options and improve outcomes, primarily in the areas of contraception, fertility and vaginal and sexual health. 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. The Company will continue to assess opportunities to expand its portfolio, while it focuses 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 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 as an option for women with hormone-receptor positive breast cancer.

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

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **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, the COVID-19 pandemic has not had a material adverse impact on the Company's business or operations, 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 clinical trial for Sildenafil Cream, 3.6% has been slower than initially expected, including as a result of operational restrictions or closure of certain study sites due to their adherence to governmental guidelines 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. For example, the Company expects clinical and nonclinical supplies for more than one of its earlier clinical stage programs will not be provided on previously anticipated timelines, in large part due to third-party supply chain and human resources constraints related to the COVID-19 pandemic, which may delay the commencement of clinical trials and nonclinical testing for these programs. Continued re-opening of the U.S. and global economies may also 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 September 30, 2021, the Company had an accumulated deficit of approximately $100.6 million, cash and cash equivalents of approximately $45.6 million, and working capital of approximately $32.3 million. For the nine months ended September 30, 2021, the Company incurred a net loss of $29.2 million and had negative cash flow from operations of approximately $18.8 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, non-clinical development 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. If the Company's commercial strategy for DARE-BV1, if approved, in the U.S. involves partnering with a commercial sales organization or co-promoting the product, its near-term funding requirements would be significantly greater than if the Company were to enter into an exclusive out-license arrangement for the commercialization of DARE-BV1.

The Company expects its operating expenses, and in particular its research and development expenses, to be significantly greater for 2021 compared to 2020, as well as for 2022 compared to 2021, as it continues to develop and seek to bring to market its product candidates, with a focus on its product candidates that have reached the human clinical study development phase.

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 will evaluate and may pursue a variety of capital raising options on an ongoing basis, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements, to cover its operating expenses, including the development, and if approved, commercialization of current and any future product candidates, and the cost of any license or other acquisition of new product candidates or technologies. The amount and timing of the Company's capital needs have been and will continue to depend highly on many factors, including the product development programs the Company chooses to pursue, the pace and results of its clinical development efforts, the commercialization strategy for its product candidates, if approved, and the nature and extent of expansion of the Company's product candidate portfolio, if any. 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.

Right-of-use, or 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 September 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 September 30, 2021 or December 31, 2020.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at September 30, 2021				
Current assets:				
Cash equivalents [1]	$ 42,583,987	$ —	$ —	$ 42,583,987
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 cash held in money market funds.

[2] Represented 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, under the heading "MBI Acquisition," and which was paid in September 2021.

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, assesses whether each good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price 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 September 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 September 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. In September 2021, the Company and Trilogic and MilanaPharm entered into another amendment to the License Agreement.

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 paid MilanaPharm $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 $250,000 of which was paid during the third quarter of 2021. The Company may also pay MilanaPharm up to $1.75 million in the aggregate upon achieving certain commercial sales milestones.

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 agreed to 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, $1.0 million of which became payable in the third quarter of 2021, and in accordance with the license agreement, the amount payable was offset by the $100,000 annual maintenance fee, resulting in a net amount of $900,000 paid during the third quarter of 2021, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the agreement.

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

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. In June 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. In July 2021, the Company’s board of directors elected to make these milestone payments in shares of the Company’s common stock, to the extent permissible under the terms of the merger agreement with MBI, and, in September 2021, the Company issued approximately 700,000 shares of its common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders’ representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021. See Note 7.

Pear Tree Acquisition

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

Milestone Payments. The Company must make contingent payments to 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 nine months ended September 30, 2021 or September 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 nine months ended September 30, 2021. The exercise price of all options granted during the nine months ended September 30, 2021 was equal to the market value of the Company's common stock on the date of grant. As of September 30, 2021, unamortized stock-based compensation expense of $4,159,122 will be amortized over a weighted average period of 2.92 years. At September 30, 2021, 152,291 shares of common stock were available 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	2,016,075	2.33
Exercised	—	—
Canceled/forfeited	—	—
Expired	—	—
Outstanding at September 30, 2021	4,802,666	$ 1.65
Exercisable at September 30, 2021	2,137,389	$ 1.42

Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 144,876	$ 60,546	$ 389,913	$ 166,639
General and administrative	$ 294,621	$ 134,336	$ 820,973	$ 375,943
Total	$ 439,497	$ 194,882	$ 1,210,886	$ 542,582

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 three and nine months ended September 30, 2021 are as follows:

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Expected life in years	6.08	5.97
Risk-free interest rate	0.97%	0.66%
Expected volatility	122%	122%
Forfeiture rate	0.0%	0.0%
Dividend yield	0.0%	0.0%
Weighted-average fair value of options granted	$1.42	$2.02

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 "at-the-market," or 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 September 30, 2021, the Company sold approximately 18.3 million shares of common stock under this agreement for gross proceeds of approximately $36.2 million and incurred offering expenses of approximately $1.2 million. During the nine months ended September 30, 2021, the Company sold approximately 26.0 million shares of common stock under this agreement for gross proceeds of approximately $46.9 million and incurred offering expenses of approximately $1.6 million.

2018 ATM Sales Agreement

In January 2018 the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC, or Wainwright, relating to the offering and sale of shares of its common stock from time to time in an ATM offering through Wainwright, acting as sales agent. In March 2021, the Company provided notice to Wainwright to terminate the agreement, and the agreement terminated in April 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.

During the nine months ended September 30, 2021, the Company sold approximately 3.3 million shares of common stock under this agreement for gross proceeds of approximately $7.7 million and incurred offering expenses of $245,000. During the nine months ended September 30, 2020, the Company sold approximately 7.9 million shares under this agreement for gross proceeds of approximately $10.8 million and incurred offering expenses of approximately $420,000.

Equity Line

In April 2020, the Company entered into a purchase agreement, or the Purchase Agreement, and a registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the Purchase Agreement, the Company had the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park was obligated to purchase up to $15.0 million of the Company's common stock.

The Company incurred legal, accounting, and other fees related to the Purchase Agreement of approximately $374,000. These costs were amortized and expensed as shares were sold under the Purchase Agreement and as of September 30, 2021 there were no unamortized costs. During the nine months ended September 30, 2021, the Company sold, and Lincoln Park purchased, 4.8 million shares under the Purchase Agreement for gross proceeds to the Company of approximately $7.0 million and recognized offering expenses of approximately $207,000. As of September 30, 2021, the Company had sold and Lincoln Park had 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 nine months ended September 30, 2021, warrants to purchase an aggregate of 265,485 shares of common stock were exercised for gross proceeds of approximately $255,000. During the nine months ended September 30, 2020, warrants to purchase an aggregate of 1,825,000 shares of common stock were exercised for gross proceeds of approximately $1.8 million. As of September 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
1,630,015	$	0.96	02/15/2023
1,643,158			

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 September 30, 2021, the Company reported operating lease ROU assets of approximately $303,000 in other non-current assets, and $368,000 and $16,000, respectively, in current portion of lease liabilities and lease liabilities long-term on the condensed consolidated balance sheet.

Total operating lease costs were approximately $134,000 and $76,000 for the three months ended September 30, 2021 and September 30, 2020, respectively, and $420,000 and $228,000 for the nine months ended September 30, 2021 and September 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 $117,000 and $111,000 for the three months ended September 30, 2021 and September 30, 2020, respectively, and $343,000 and $349,000 for the nine months ended September 30, 2021 and September 30, 2020, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. Further, at September 30, 2021, operating leases had a weighted average remaining lease term of 0.81 years.

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

Remainder of 2021	$	119,000
2022		278,000
Total future minimum lease payments		397,000
Less: accreted interest		13,000
Total operating lease liabilities	$	384,000

7. COMMITMENTS AND CONTINGENCIES

CRADA with NICHD for the Pivotal Phase 3 Study of Ovaprene

In July 2021, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene, or the Ovaprene Phase 3. The Ovaprene Phase 3 will be conducted within NICHD's Contraceptive Clinical Trial Network with NICHD contractor Health Decisions Inc., a contract research organization, providing clinical coordination and data collection and management services for the Ovaprene Phase 3. The Company and NICHD will each provide medical oversight and final data review and analysis for the Ovaprene Phase 3 and will work together to prepare the final report of the results of the Ovaprene Phase 3. The Company is responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in payments to NICHD to be applied toward the costs of conducting the Ovaprene Phase 3. NICHD will be responsible for the other costs related to the conduct of the Ovaprene 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. The Company's remaining obligation under the CRADA at September 30, 2021 is $5.25 million.

Contingent Consideration

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

Note Payable

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

8. GRANT AWARDS

NICHD Non-Dilutive Grant Funding

The Company has received notices of awards and non-dilutive grant funding from the 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 nine months ended September 30, 2021 and approximately $167,000 and $459,000 during the three and nine months ended September 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 ongoing. Additional potential funding of up to approximately $2.0 million for the "Phase II" segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds. There is no guarantee the Company will receive any Phase II award.

The Company recorded credits to research and development expense for costs related to the NICHD award of approximately $38,000 and $64,000 during the three and nine months ended September 30, 2021, respectively. At September 30, 2021, the Company recorded a receivable of approximately $50,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

DARE-LARC1

In September 2021, the Company received a notice of award of a grant from NICHD to support the development of DARE-LARC1. The award in the amount of approximately $300,000 is to be used to explore device insertion and removal in non-clinical studies, which is to occur during the period of September 2021 through August 2022.

The Company did not record any credits to research and development expense for costs related to the NICHD award during the three or nine months ended September 30, 2021 and did not record a receivable for expenses incurred through such date that it believes is eligible for reimbursement under the grant.

DARE-LARC1 Non-Dilutive Grant Funding

MBI Grant Agreement

The Company's wholly-owned subsidiary, MBI, 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 September 30, 2021, all payments under this agreement associated with research and development expenses for DARE-LARC1 had been incurred and reported to the Foundation.

2021 DARE-LARC1 Grant Agreement

In June 2021, the Company entered into an agreement with the Foundation, or the 2021 DARE-LARC1 Grant Agreement, under which the Company was awarded up to $48.95 million to support the development of DARE-LARC1. The 2021 DARE-LARC1 Grant Agreement will support technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 in non-clinical proof of principle studies. The Company received an initial payment of $11.45 million in July 2021. Additional payments are contingent upon the DARE-LARC1 program’s achievement of specified development and reporting milestones. At September 30, 2021, approximately $11.2 million of 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options	4,802,666	2,783,591	4,802,666	2,783,591
Warrants	1,643,158	1,908,643	1,643,158	1,908,643
Total	6,445,824	4,692,234	6,445,824	4,692,234

10. SUBSEQUENT EVENTS

October 2021 ATM Sales Agreement

On October 13, 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. The Company agreed to pay a commission equal to 3.0% of the gross proceeds of any common stock sold under the agreement, plus certain legal expenses. Shares of the Company's common stock sold under the agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-254862) and the base prospectus included therein, originally filed with the SEC on March 30, 2021, and declared effective on April 7, 2021, and the prospectus supplement dated October 13, 2021 relating to the offering of up to $50.0 million in shares of the Company's common stock under this sales agreement, and any subsequent prospectus supplement filed with the SEC related to this ATM equity offering program.

Second Scheduled Payment to NICHD under CRADA

In November 2021, the Company paid $1.25 million to NICHD in accordance with the payment schedule under the CRADA toward the costs of the Ovaprene Phase 3.

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 prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, fertility and vaginal and sexual health. Our business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid to late-stage clinical development, 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. We will continue to assess opportunities to expand our portfolio, while we focus 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 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 as an option for women with hormone-receptor positive breast cancer.

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

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **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 product candidates in human clinical studies, specifically our product candidates DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%, and plan to continue to focus our resources on these and other product candidates that have reached the human clinical study development phase 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 reimposing restrictions in various geographies. To date, the COVID-19 pandemic has not had a material adverse impact on our business or operations, 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 clinical trial for Sildenafil Cream, 3.6% has been slower than initially expected, including as a result of operational restrictions or closure of certain study sites due to their adherence to governmental guidelines 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 our needs. For example, we expect clinical and nonclinical supplies for more than one of our earlier clinical stage programs will not be provided to us on previously anticipated timelines, in large part due to third-party supply chain and human resources constraints related to the COVID-19 pandemic, which may delay commencement of clinical trials and nonclinical testing for these programs. Continued re-opening of the U.S. and global economies may also 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 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 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 a new drug application, or NDA, 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 an NDA for DARE-BV1 for the treatment of bacterial vaginosis to the FDA in June 2021, and in August 2021, the FDA accepted for filing our NDA, 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. The PDUFA target action date for the DARE-BV1 NDA is December 7, 2021.

When we submitted the DARE-BV1 NDA to the FDA in June 2021, we paid a $2.9 million 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 received a full refund of the fee in August 2021.

If the FDA approves the NDA in December 2021, we would expect a commercial launch of DARE-BV1 in the United States in the first half of 2022. We are engaged in ongoing strategic discussions and evaluation of the commercialization strategy for DARE-BV1, and in other activities to support a robust market introduction of the product in 2022, if approved. We currently intend to announce our commercialization strategy for DARE-BV1 in the U.S. by the end of this year. Commercialization arrangements 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. 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 the active pharmaceutical ingredient, or 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 that DARE-BV1's product profile, together with the commercial-readiness work we have done and are doing, will enable a commercial launch of DARE-BV1 in the U.S. on the timeline we have planned, if the FDA approves the NDA in 2021.

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 has been slower than initially expected. We identified a number of contributing factors, and we implemented mitigation strategies to increase study subject recruitment. 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. The slower pace of enrollment in the early months of the study lengthened our timeline for the study, which may increase the overall cost of the study compared to our prior estimate. 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 $20.0 million, less than half of which will be fiscal 2021 expenses.

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 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. We are currently evaluating the development and regulatory strategies for our ongoing clinical development for DARE-HRT1. 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

In September 2021, we announced initiation of our Phase 1/2 clinical study of DARE-VVA1, a novel intravaginal tamoxifen product being developed for the treatment of moderate to severe vulvar and vaginal atrophy, or VVA. The randomized, double-blind, placebo-controlled, dose-ranging study is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of DARE-VVA1 in postmenopausal participants with moderate to severe VVA and is being conducted by our wholly owned Australian subsidiary. We expect the study will enroll approximately 40 postmenopausal women with VVA, including a cohort of women with a history of hormone-receptor positive breast cancer, at approximately three study sites. We anticipate reporting topline data from the study in 2022.

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, or otherwise. 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

New ATM Sales Agreement

On October 13, 2021, we entered into a new 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 acts as our agent. SVB Leerink also acts as our sales agent under an ATM sales agreement we entered into in April 2021. As with the April 2021 sales agreement with SVB Leerink, under the October 2021 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 October 2021 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 October 2021 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 October 2021 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. We have no obligation to sell any shares under the October 2021 sales agreement, and we may suspend solicitation and offers under the 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 agreement. Shares of our common stock sold under the October 2021 sales agreement 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 October 13, 2021, relating to the offering of up to $50.0 million in shares of our common stock under the October 2021 sales agreement and any subsequent prospectus supplement related to the offering of shares of our common stock under the October 2021 sales agreement.

NICHD Grant Awarded for DARE-LARC1

In September 2021, we received a Notice of Award of a grant in the amount of approximately $300,000 from NICHD to support the development of DARE-LARC1. The grant funding is to be used to explore device insertion and removal in non-clinical studies during the period of September 2021 through August 2022.

FDA Acceptance of DARE-BV1 NDA and Waiver and Refund of Application Fee

In August 2021, the FDA accepted for filing and granted Priority Review for our NDA for DARE-BV1 for the treatment of bacterial vaginosis and 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 received the refund in August 2021.

***Receipt* of Payment under 2021 DARE-LARC1 Grant Agreement**

In July 2021, we received an initial payment of $11.45 million under the grant agreement we entered into in June 2021 for up to $48.95 in non-dilutive grant funding to support the development of DARE-LARC1. See Note 8 to our unaudited condensed consolidated financial statements contained in this report. Our receipt of any additional payments under this grant agreement is contingent upon the DARE-LARC1 program’s achievement of specified development and reporting milestones.

CRADA with NICHD for Pivotal Phase 3 Study of Ovaprene

In July 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 we paid in November 2021, in accordance with the payment schedule under the CRADA. 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.

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. In June 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 had 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 was required to 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, to the extent permissible, and in September 2021, we issued approximately 700,000 shares of our common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders’ representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

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 September 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 September 30,		Change
	2021	2020	$
Operating expenses:			
General and administrative	$ 2,211,334	$ 1,353,069	$ 858,265
Research and development	10,432,603	6,203,753	4,228,850
License fees	25,000	25,000	—
Total operating expenses	12,668,937	7,581,822	5,087,115
Loss from operations	(12,668,937)	(7,581,822)	(5,087,115)
Other income	1,508	(986)	2,494
Net loss	$ (12,667,429)	$ (7,582,808)	$ (5,084,621)
Deemed dividend from trigger of down round provision feature	$ —	$ (6,863)	6,863
Net loss to common shareholders	$ (12,667,429)	$ (7,589,671)	$ (5,077,758)
Other comprehensive loss:			
Foreign currency translation adjustments	(63,281)	672	(63,953)
Comprehensive loss	$ (12,730,710)	$ (7,588,999)	$ (5,141,711)

Revenues

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

General and administrative expenses

The increase of $858,265 in general and administrative expenses for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 was primarily attributable to increases in professional services expense of approximately $291,000, commercial-readiness expenses of approximately $245,000, personnel costs of approximately $193,000, stock-based compensation expense of approximately $160,000, and insurance expense of approximately $100,000, partially offset by decreases in facilities and office expenses of approximately $151,000.

We expect an increase in general and administrative expenses of approximately 20% for 2021 compared to 2020**,** primarily due to increased personnel expenses and other general corporate overhead. While this estimate takes into account the costs of DARE-BV1 commercial readiness activities we have conducted or plan to conduct regardless of the commercial strategy we pursue for DARE-BV1 in the U.S., if we determine to partner with a commercial sales organization or to co-promote the product, the increase in our general and administrative expenses for 2021 compared to 2020 could be greater than anticipated.

Research and development expenses

The increase of approximately $4.2 million in research and development expenses for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 was primarily attributable to increased costs for two of our clinical-stage product candidates, Sildenafil Cream 3.6% and Ovaprene, with approximately $4.8 million related to the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene. Also contributing to the increase were increases in (a) costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $1.7 million, (b) personnel costs of approximately $123,000, and (c) stock-based compensation expense of approximately $84,000. Such increases were partially offset by a decrease in development costs of approximately $2.6 million as a result of the completion of the DARE-BV1 Phase 3 clinical trial in December 2020.

Our research and development expenses for 2021 may be, and are on track to be, approximately double our research and development expenses for 2020.

License fees

For the three months ended September 30, 2021 we accrued $25,000 of the $100,000 annual license maintenance fee payable in the second quarter of 2022 under our license agreement related to DARE-HRT1.

For the three months ended September 30, 2020 we accrued $25,000 of the $100,000 license maintenance fee payable in the second quarter of 2021 under our license agreement related to DARE-HRT1.

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

Other income

The increase of $2,494 in other income for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 was primarily due to an increase in interest earned on cash balances in the current period.

Comparison of Nine Months Ended September 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:

	Nine months ended September 30,		Change
	2021	2020	$
Operating expenses:			
General and administrative	$ 5,949,299	$ 4,772,382	$ 1,176,917
Research and development	23,501,098	14,131,007	9,370,091
License fees	75,000	58,333	16,667
Total operating expenses	29,525,397	18,961,722	10,563,675
Loss from operations	(29,525,397)	(18,961,722)	(10,563,675)
Other income	1,686	2,454	(768)
Gain on extinguishment of note payable	369,887	—	369,887
Net loss	$ (29,153,824)	$ (18,959,268)	$ (10,194,556)
Deemed dividend from trigger of down round provision feature	—	(6,863)	6,863
Net loss to common shareholders	$ (29,153,824)	$ (18,966,131)	$ (10,187,693)
Other comprehensive loss:			
Foreign currency translation adjustments	(79,002)	(10,182)	(68,820)
Comprehensive loss	$ (29,232,826)	$ (18,976,313)	$ (10,256,513)

Revenues

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

General and administrative expenses

The increase of approximately $1.2 million in general and administrative expenses for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 was primarily attributable to increases in personnel costs of approximately $558,000, stock-based compensation expense of approximately $445,000, commercial readiness expense of approximately $245,000, and professional expenses of approximately $62,000, partially offset by decreased facilities and office expenses of approximately $244,000.

Research and development expenses

The increase of approximately $9.4 million in research and development expenses for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 was primarily attributable to increased costs for two of our clinical-stage product candidates, Sildenafil Cream, 3.6% and Ovaprene, with approximately $8.4 million related to the Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene. Also contributing to the increase were increases in (a) costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $3.3 million, (b) costs for activities related to our preclinical product candidates of approximately $380,000, (c) personnel costs of approximately $300,000, and (d) stock-based compensation expense of approximately $223,000. Such increases were partially offset by a decrease in development costs of $3.5 million as a result of the completion of the DARE-BV1 Phase 3 clinical trial in December 2020.

License fees

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

For the nine months ended September 30, 2020 we accrued $58,333 of the $100,000 license maintenance fee payable in the second quarter of 2021 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 $768 in other income for the nine months ended September 30, 2021 as compared to the nine months ended September 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 the loan we obtained under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, administered by the U.S. Small Business Administration, or the SBA, 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 September 30, 2021, our accumulated deficit was approximately $100.6 million, our cash and cash equivalents were approximately $45.6 million, and our working capital was approximately $32.3 million. We incurred a loss from operations of approximately $29.2 million, and had negative cash flow from operations of approximately $18.8 million during the nine months ended September 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 development 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. If our commercial strategy for DARE-BV1, if approved, in the U.S. involves partnering with a commercial sales organization or co-promoting the product, our near-term funding requirements would be significantly greater than if we enter into an exclusive out-license arrangement for the commercialization of DARE-BV1. Regardless of our commercial strategy for DARE-BV1, as discussed above, we expect our operating expenses, and in particular our research and development expenses, to be significantly greater for 2021 compared to 2020, as well as for 2022 compared to 2021, as we continue to develop and seek to bring to market our product candidates, with a focus on our product candidates that have reached the human clinical study development phase.

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 and predominantly from sales of shares of our common stock. During the nine months ended September 30, 2021, we received approximately $52.7 million of net proceeds from the sales of approximately 29.3 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 $255,000 upon the exercise of warrants.

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 agreements, 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. For the foreseeable future, we will evaluate and may pursue a variety of capital raising options on an ongoing basis, 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 current and any future product candidates, and the cost of any license or other acquisition of new product candidates or technologies. The amount and timing of our capital needs have been and will continue to depend highly on many factors, including the product development programs we choose to pursue, the pace and results of our clinical development efforts, our commercialization strategy for our product candidates, if approved, and the nature and extent of expansion of our product candidate portfolio, if any. 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:

	Nine months ended September 30,	
	2021	2020
Net cash used in operating activities	$ (18,848,138)	$ (16,041,176)
Net cash used in investing activities	(14,524)	(15,246)
Net cash provided by financing activities	59,842,978	16,675,911
Effect of exchange rate changes on cash and cash equivalents	(79,002)	(10,182)
Net increase in cash and cash equivalents	$ 40,901,314	$ 609,307

Net cash used in operating activities

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

Cash used in operating activities for the nine months ended September 30, 2020 included the net loss of $19.0 million, decreased by non-cash stock-based compensation expense of approximately $543,000. Components providing operating cash were an increase of approximately $472,000 in accounts payable, an increase of approximately $1.0 million in deferred license revenue, a decrease of approximately $342,000 in other receivables, an increase of approximately $355,000 in accrued expenses, an increase of approximately $159,000 in deferred grant funding, a decrease of approximately $118,000 in other non-current assets, and an increase of approximately $18,700 in prepaid expenses.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2021 and 2020 consisted of approximately $59.8 million and $16.7 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 after fees and expenses, and primarily from sales of shares of our common stock under our ATM sales agreement after fees and expenses and upon the exercise of warrants during the prior period.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2021 and September 30, 2020 was $14,524 and $15,246, respectively.

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 September 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, the path to marketing approval could be considerably longer and more expensive than anticipated and, even if the deficiencies identified by the FDA are minor, 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. 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 potentially inspection reports regarding one or more of 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 DARE-BV1 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 we were to discontinue development of DARE-BV1 as a result of a CRL, we may never get a return on our investment in the program. If a CRL is issued, even if the deficiencies identified therein are minor, there may be an immediate and significant decrease in the market price of our common stock, and our reputation could suffer, in particular because, as an organization, this is the first NDA we have submitted, which could significantly harm our ability to raise additional capital to fund our operations and the continued development of our product candidates. In addition, a significant drop in the market price of our common stock as a result of a CRL may subject us to class action securities lawsuits (regardless of their merit), which could be lengthy and expensive and divert our management's attention. Accordingly, the issuance of a CRL 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.

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 within the timeframe we currently anticipate, 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. In addition, vaccination mandates may lead to human resource constraints at our CROs, CMOs and other third parties on which we rely if substantial proportions of their workforce quit or are terminated for refusing to comply with vaccination mandates.

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. To date, the COVID-19 pandemic has contributed to a slower than anticipated pace of enrollment of participants in our Phase 2b clinical study of Sildenafil Cream, 3.6% as a result of operational restrictions or closure of certain study sites due to their adherence to governmental guidelines intended to reduce the spread of COVID-19, and commencement of clinical trials and nonclinical testing for more than one of our earlier clinical stage programs may be delayed due to delays in supplies needed for those studies as a result of third-party supply chain and human resources constraints, in large part related to the COVID-19 pandemic.

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 have evolved and must continue to 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 FSAD, are complex and there is limited clinical trial precedent from which to draw experience, making the design and execution of a clinical trial that demonstrates effectiveness of Sildenafil Cream, 3.6% in treating FSAD more inherently challenging and uncertain compared with investigational products for many other conditions.

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, 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%. For example, we expect to randomize 400 to 590 subjects into our Phase 2b study of Sildenafil Cream, 3.6%. Due to the study's adaptive design, the final study sample size has not yet been determined. If the study requires a number of randomized subjects, on the high end of that range, the study could take significantly longer and be significantly more expensive to complete than if the final size of the study need only be on the low end of that range., If we are unable to efficiently and successfully complete our Phase 2b clinical trial of Sildenafil Cream, 3.6%, product development costs for the program would increase significantly, and such failure could negatively impact the perception of the program's potential for future clinical and regulatory success, either of which 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, or provide them at the agreed upon price and timeline or to our requisite quality standards, including due to geopolitical actions, natural disasters, public health emergencies or pandemics, such as the COVID-19 pandemic, or poor workforce relations or human capital management. We rely on the efforts of these third parties and if they fail to perform as expected, we could suffer significant delays and additional costs 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 DARE-BV1 is approved but healthcare providers do not view the prescribing information for our product, including the cure rates that DARE-BV1 demonstrated in its clinical studies as compelling compared with 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 grants supporting the DARE-LARC1 program do 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 grants supporting pre-clinical development of DARE-LARC1, including the grant agreement under which we were awarded up to $48.95 million in non-dilutive funding for pre-clinical development of DARE-LARC1 do 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 in July 2021, 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 and the value of our development programs to our company.

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. 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.

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.

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

On September 1, 2021, in accordance with the terms of our merger agreement with MBI, dated as of November 10, 2019, we issued an aggregate of approximately 700,000 shares of our common stock to former stockholders of MBI as payment in part for additional consideration payable upon the achievement of milestones, as described in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, of this report under "Recent Events – Milestone Payments to Former MBI Stockholders." The shares were issued in transactions not involving a public offering pursuant to Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act.

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	Amendment to License Agreement effective as of September 21, 2021 by and among Daré Bioscience, Inc., TriLogic Pharma, LLC and MilanaPharm LLC					X
10.2+	Cooperative Research and Development Agreement entered into as of July 8, 2021 between Dare Bioscience, Inc. and the Eunice Kennedy Schriver National Institutes of Child Health and Human Development Institute					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 is the type that we treat as private or confidential.

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: November 10, 2021

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

Date: November 10, 2021

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

Second Amendment to License Agreement

This Second Amendment to License Agreement ("Amendment") is effective as of September 21, 2021 (the "Second Amendment Date") and is made by and among Daré Bioscience, Inc., a Delaware corporation ("Daré"), and TriLogic Pharma, LLC, a Delaware limited liability company ("TriLogic"), and MilanaPharm LLC, a Delaware limited liability company ("MilanaPharm," and individually and collectively with Trilogic each a "Licensor" and together "Licensors"). Licensors and Daré are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

BACKGROUND

A. Licensors and Daré are parties to that certain Exclusive License Agreement effective as of January 9, 2017, as amended by the Parties on December 5, 2018 (together, the "Original Agreement").

B. The Parties wish to again amend the Original Agreement such that Daré shall acquire primary responsibility for the Licensed Patents, subject to the conditions recited herein.

C. Capitalized terms used but not defined in this Amendment have the meanings ascribed to them in the Original Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. Amendments. The Original Agreement is amended as follows, with such amendments effective as of the Second Amendment Date.

2. Section 4.3.5. Section 4.3.5 is deleted in its entirety.

3. Section 6 Amendments.

Section 6.1 and 6.2 are replaced in their entirety with the following:

6.1 Prosecution. As between Licensors on the one hand and Daré on the other hand, Daré shall have the first right to prepare, file, prosecute and maintain the Licensed Patents (including without limitation U.S. Patent Application No. 62/194,518 and all Patent Rights issuing from or claiming priority to such application) during the term of this Agreement, at Daré's sole cost and expense. Daré shall keep Licensors fully informed of all steps with regard to the preparation, filing, prosecution, and maintenance of the Licensed Patents, including providing Licensors with a copy of material communications to and from the applicable patent authority regarding such Licensed Patents, and providing Licensors drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for

Licensors to review and comment thereon. Daré shall reasonably take into consideration all reasonable comments made by Licensors on matters related to prosecution, maintenance and enforcement related to the Licensed Patents; *provided, however*, that for the avoidance of doubt, Daré shall have the exclusive right to make all patent prosecution decisions.

6.2 Decision Not to Prosecute. In the event that Daré decides not to prepare, file, prosecute, or maintain any Licensed Patent in any country or jurisdiction, Daré shall provide reasonable prior written notice to Milanapharm of such intention (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Licensed Patent in such country or jurisdiction). Either of the Licensors shall thereupon have the option, in their sole discretion and as agreed between them, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Licensed Patent at its or their expense in such country or jurisdiction. If a Licensor exercise this option, then it shall promptly notify Daré thereof, and provide written instructions that are submitted by both Licensors jointly to Daré to transfer control of such Licensed Patent to counsel instructed jointly by the Licensors. Each Licensor shall indemnify and hold Daré and its affiliates harmless from and against any clam, action, proceeding, damage, loss, cost and expense, including reasonable attorneys' fees, resulting from Daré's carrying out such instructions.

4. Transfer. Licensors will, within ten (10) business days of the Effective Date, deliver or cause its counsel to deliver to Daré true and correct copies of all files, documents and correspondence related to the filing, maintenance and prosecution of the Licensed Patents, reasonably necessary for Daré to assume its prosecution rights hereunder as reasonably necessary for Daré and its counsel to assume its prosecution rights hereunder, and shall direct its counsel to cooperate in the transition of such matters to Daré. Licensors shall also perform all such acts and execute all such agreements, assurances and other documents and instruments as Daré reasonably requests (i) to perfect the rights and powers afforded, created or intended to be afforded or created by this Amendment or to give full force and effect to, or facilitate the performance of, the transactions provided for in this Amendment; and (ii) with regard to any prosecution matters regarding the Licensed Patents.

5. Miscellaneous. This Amendment shall be effective from the Second Amendment Date and in full force and effect until the expiration or termination of Original Agreement. Except as expressly provided in this Amendment, the Original Agreement remain unmodified and in full force and effect.

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be signed in duplicate by their duly authorized representatives.

Daré Bioscience, Inc.

By: /s/ Sabrina Johnson

Print Name: Sabrina Johnson

Title: CEO

Trilogic Pharma, LLC

By: /s/ James Harwick

Print Name: James Harwick

Title: CEO

MilanaPharm LLC

By: /s/ James Harwick

Print Name: James Harwick

Title: CEO

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.

Cooperative Research And Development Agreement

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

This Cover Page identifies the Parties to this CRADA:

The U.S. Department of Health and Human Services, as represented by
***Eunice Kennedy Shriver* National Institute of Child Health and Human Development**
an Institute, Center, or Division (hereinafter referred to as the "NICHD" of the
National Institutes of Health (NIH)

and

Daré Bioscience, Inc.,
hereinafter referred to as "Daré",
created and operating under the laws of **Delaware**.

1. Preamble

The National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), and the Food and Drug Administration (“FDA”), which are agencies within the Department of Health and Human Services (“HHS”) have the authority to enter into a Cooperative Research and Development Agreement (“CRADA”) under 15 USC §3710a. It is under this authority that this agreement is executed. Collectively or individually, Daré and NICHD shall also be referred to as “Parties” or “Party.”

This CRADA between NICHD and Daré will be effective when signed by the Parties. The official contacts for the Parties are identified on the Contacts Information Page. Publicly available information regarding this CRADA appears on the Summary Page. The research and development activities that will be undertaken by NICHD and Daré in the course of this CRADA are detailed in the Research Plan, attached as Appendix A.

If a definition of a term as provided in Article 2 conflicts with the definition in the applicable sections of either the United States Code (U.S.C.) or the Code of Federal Regulations (C.F.R.), the definition in the U.S.C. or C.F.R. will control.

2. Definitions

Affiliate: “Affiliate” means any corporation or other business entity controlled by, controlling, or under common control with Daré at any time during the term of the CRADA. For this purpose, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.

Background Invention: "Background Invention" means an Invention conceived and first actually reduced to practice outside of the scope of the Research Plan.

Certificate of Confidentiality: "Certificate of Confidentiality" or "CoC" means the certificate issued by the NIH pursuant to Section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) that protects the privacy of Human Subjects enrolled in the Protocol. With limited exceptions defined in 42 U.S.C. § 241(d), the CoC protects from disclosure names or any information, documents, or biospecimens containing ISI collected under a Protocol conducted under this CRADA.

Clinical Investigator: "Clinical Investigator" means, in accordance with 21 C.F.R. § 312.3, an individual who actually conducts a clinical investigation, that is, who directs the administration or dispensation of Test Article to a Human Subject, and who assumes responsibility for studying Human Subjects, for recording and ensuring the integrity of research data, and for protecting the welfare and safety of Human Subjects. Clinical Investigators may also conduct studies that are non-clinical in nature. For this CRADA, a Clinical Investigator will be responsible for conducting the Study at a Clinical Research Site.

Clinical Research Site: “Clinical Research Site(s)” means the extramural site(s) at which the Study described in the Research Plan will be performed. The Clinical Research Sites are providing services as either contractors or subcontractors of NICHD under a funding agreement as defined under 35 U.S.C. § 201(b). The Clinical Research Sites are not parties to this CRADA.

Confidential Information: “Confidential Information” means confidential scientific, business, or financial information provided by either Party to the other Party in connection with this Agreement. Confidential Information does not include the following:

(a) information that is publicly known or that is available from public sources at the time of disclosure, or that becomes publicly known or available from public sources after disclosure through no fault of the receiving Party;

(b) information that is already known by the receiving Party other than from the disclosing Party, or information that is independently created or compiled by the receiving Party, without reference to or use of the Confidential Information of the disclosing Party;

(c) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan; or

(d) CRADA Data or descriptions of CRADA Materials, which are subject to separate confidentiality obligations as set forth herein.

Coordinating Center: "Coordinating Center" means Health Decisions Inc., a contractor of NICHD and a contract research organization located in Durham, North Carolina, which will provide clinical coordination and data collection and management services for the Study. The Coordinating Center is not a party to this CRADA.

CRADA Data: “CRADA Data” means all recorded information first produced in the performance of the Research Plan. This includes data and results generated by the Parties, the Clinical Research Sites, and the Coordinating Center. CRADA Data will not include IPI or ISI.

CRADA Materials: “CRADA Materials” means all tangible materials first produced in the performance of the Research Plan.

CRADA Subject Invention: "CRADA Subject Invention" means any Invention of any Party, conceived or first actually reduced to practice in its performance of the Research Plan.

Effective Date: “Effective Date” means the date of the last signature of the Parties executing this CRADA.

FDA: "FDA" means the U.S. Food and Drug Administration.

Government: “Government” means the Government of the United States of America.

Human Subject: "Human Subject" means, in accordance with the definition in 45 C.F.R. § 46.102(f), a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual; or (b) Identifiable Private Information.

IDE: “IDE” means an “Investigational Device Exemption,” filed in accordance with 21 C.F.R. Part 812 under which clinical investigation of an experimental device (Test Article) is performed in Human Subjects in the United States or intended to support a United States licensing action.

IDE Sponsor: “IDE Sponsor” means, in accordance with the definition in 21 C.F.R. § 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing clinical trials with Test Articles; for this CRADA, the IDE Sponsor is Daré.

Invention: "Invention" means any invention, whether or not covered by a patent or patent application, or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, the Plant Variety Protection Act, 7 U.S.C. §§ 2321 *et seq.* or foreign patent law.

Investigator’s Brochure: “Investigator’s Brochure” means a document containing critical and useful information about the Test Article, and may include a description of the device and its accessories and components, a summary of the pre-clinical testing and data, and a risk-benefit analysis.

Identifiable Private Information (IPI): “Identifiable Private Information” or “IPI” about a Human Subject means private information from which the identity of the subject is or may readily be ascertained. Regulations defining and governing this information include 45 C.F.R. Part 46 and 21 C.F.R. Part 50.

Identifiable Sensitive Information: “Identifiable Sensitive Information” or “ISI” means, in accordance with the definition of 42 U.S.C. § 241(d)(4), information that is about an individual and that is gathered or used during the course of research as described in 42 U.S.C. § 241 (d)(1)(A) through which an individual is identified, or that includes IPI, or for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identify of an individual.

IRB: "Institutional Review Board" or "IRB" means, in accordance with 45 C.F.R. Part 46, 21 C.F.R. Part 56, and other applicable regulations, an independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of the Human Subjects involved in a study.

Joint CRADA Subject Invention: "Joint CRADA Subject Invention" means any CRADA Subject Invention made jointly by both Daré and NIH employee(s) or other entity which is required to assign CRADA Subject Inventions to either Daré and/or NIH.

Patent Application: “Patent Application” means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office or the corresponding patent issuing authority of another nation.

Patent: "Patent" means, for a CRADA Subject Invention, any issued United States or foreign patent, any international counterpart(s), and any corresponding grant(s) by a non-U.S. government in place of a patent.

Principal Investigator: “Principal Investigator(s)" or “PI(s)” means the person(s) designated by the Parties who will be responsible for the conduct of the Research Plan. For this CRADA, NICHD’s PI is Diana Blithe, PhD and Daré’s PI is Christine Mauck, MD, MPH.

Progress Report: "Progress Report" means a brief report of the progress of an IDE-associated investigation which the IDE Sponsor is required to submit to the IRB or FDA (or both), as appropriate under 21 C.F.R. § 812.150(b)(5).

Protocol: “Protocol” means the formal, detailed description of a study to be performed as provided for in the Research Plan. It describes the objective(s), design, methodology, statistical considerations, and organization of a trial. For the purposes of this CRADA, the term Protocol, for clinical research involving Human Subjects, includes any and all associated documents, including informed consent forms, to be provided to Human Subjects and potential participants in the Study. A Protocol may include analytical assays or ancillary correlative studies conducted in conjunction with the clinical study.

Raw Data: "Raw Data" means the primary quantitative and empirical data first collected from experiments and clinical trials conducted within the scope of this CRADA, including but not limited to information contained in case report forms. Raw Data may contain IPI. Raw Data is excluded from CRADA Data.

Research Plan: “Research Plan” means the statement in Appendix A of the respective research and development commitments of the Parties.

Sole CRADA Subject Invention: "Sole CRADA Subject Invention" means any CRADA Subject Invention made by employee(s) or other person or entity which is required to assign CRADA Subject Inventions solely to either NICHD or Daré, as applicable.

Study: “Study” means the multi-center, non-comparative, pivotal Phase III contraceptive study to evaluate the effectiveness of the Test Article (Ovaprene®) as a contraceptive device, as described under the Research Plan and to be conducted in accordance with the Protocol.

Test Article: "Test Article" means, in accordance with 21 C.F.R. § 50.3(j), any drug (including a biological product, medical device, food additive, color additive, electronic product, or any other article) subject to regulation under the Federal Food, Drug, and Cosmetic Act that is intended for administration to humans or animals, as identified in the Research Plan. For this CRADA, the Test Article is Daré’s proprietary Ovaprene® contraceptive device.

3. Patenting & Licensing

3.1 **Ownership of CRADA Subject Inventions.** Ownership of and title to all Sole CRADA Subject Inventions will vest with the owning Party, subject to the Government license described in this Article 3. The Parties will own jointly all Joint CRADA Subject Inventions. The Clinical Research Sites and the Coordinating Center are NICHD's contractors or subcontractors and are not parties to this CRADA. This CRADA does not grant to Daré any rights to Inventions made by any of NICHD's contractors or subcontractors. Contractors may elect and retain title to inventions developed under the contract per the provisions of the Bayh-Dole Act (35 U.S.C. § 200, *et. seq.*).

3.2 **Copies of Patent Applications.** The Parties will promptly provide a copy of any Patent Applications claiming CRADA Subject Inventions that it filed to the respective CRADA Notices contacts identified on the Contacts Information Page. These filings will be treated as Confidential Information in accordance with Article 4 concerning Data and Materials.

3.3 **Patent Strategy on Joint CRADA Subject Inventions.**

a) NIH and Daré will discuss in advance a patent filing strategy on any Joint CRADA Subject Invention, including the decision about whether to file a Patent Application and which Party will file on behalf of both Parties.

b) The Party filing a Patent Application on Joint CRADA Subject Inventions will provide the non-filing Party with a copy of any communication to or from a patent office relating to prosecution of the Patent Application within thirty (30) days of transmission or receipt of the communication. The filing Party will also provide the other Party with the power to inspect and make copies of all documents retained in the applicable Patent Application or Patent file. NIH and Daré will cooperate with each other to obtain necessary signatures on Patent Applications, assignments, or other documents.

c) In the event that the filing Party intends to abandon, allow to lapse or otherwise discontinue prosecution or maintenance of any or all Patent Applications or Patents on Joint CRADA Subject Inventions, the non-filing Party will have the right to assume responsibility for prosecution and maintenance using patent counsel of its own choice. The filing Party will give sufficient notice of such intention to allow transfer to the non-filing Party and will render all necessary assistance to allow the non-filing Party to continue with prosecution and maintenance.

3.4 **Statement in Patent of Government CRADA.** Daré will place the following statement in any Patent Application it files claiming CRADA Subject Inventions: "This invention was made in the performance of a Cooperative Research and Development Agreement with the National Institutes of Health. The Government of the United States has certain rights in this invention." This statement refers to the Government use license required under 15 U.S.C. § 3710a(b)(2).

3.5 **Statement in Patent for Joint CRADA Subject Invention.** If NIH files a Patent Application on a Joint CRADA Subject Invention, it will include a statement within the Patent Application that clearly identifies the Parties and states that the Joint CRADA Subject Invention was made under this CRADA.

3.6 **Patent Expenses.** Unless agreed otherwise, the Party filing a Patent Application will be responsible for all expenses and fees in connection with the preparation, filing, prosecution, and maintenance of any Patent Applications and Patents.

3.7 **Rights in Background Inventions.** Nothing in this CRADA will be construed to grant any rights in one Party's Background Invention(s) to another Party, except to the extent necessary for the Parties to conduct the activities described in the Research Plan.

3.8 **Daré License Option to CRADA Subject Inventions.** With respect to Government rights to any NICHD Sole CRADA Subject Invention or Joint CRADA Subject Invention for which a Patent Application was filed, NIH hereby grants to Daré an exclusive option to elect an exclusive or nonexclusive (at Daré's election) development and commercialization license to such Government rights. The field of use to any commercial license granted pursuant to this option will be commensurate with the scope of the Research Plan. To exercise this license option, Daré must submit a written notice to the NIH CRADA Notices Contact identified on the Contacts Information Page within [**] after either (i) Daré receives written notice from NIH that the Patent Application has been filed or (ii) the date on which Daré files the Patent Application. The written notice exercising this option will include a completed license application which can be found on the website for the NIH Office of Technology Transfer (www.ott.nih.gov) and will initiate a negotiation period that expires [**] after the exercise of the option. The negotiation period may be extended by NIH as long as both Parties are negotiating in good faith. Per Section 3.1, the license option described under this Section 3.8 does not apply to any Invention made or discovered by any of NICHD's contractors or subcontractors.

3.9 **Government Rights to CRADA Subject Inventions.** NICHD and Daré agree that they have the following statutory obligations:

a) Pursuant to 15 U.S.C. § 3710a(b)(1)(A), in any grant of a license to the Government's interest in NICHD's Sole CRADA Subject Inventions or Joint CRADA Subject Inventions to Daré, the Government shall retain a non-exclusive, nontransferable, irrevocable, paid-up license from Daré to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of section 552(b)(4) of Title 5 or which would be considered as such if it had been obtained from a non-Federal party;

b) Pursuant to 15 U.S.C. § 3710a(b)(2), Daré agrees to grant to the Government a nonexclusive, non-transferable, irrevocable, paid-up license to practice or have practiced throughout the world by or on behalf of the Government for research or other Government purposes its Sole CRADA Subject Inventions; and

c) For any exclusive license that the Government grants in NICHD's Sole CRADA Subject Inventions or in its interest in a joint CRADA Subject Invention, the Government shall retain the rights set forth in 15 U.S.C. § 3710a(b)(1)(B and C).

3.10 **Reservation of Daré License Option to CRADA Subject Inventions.** For an NICHD Sole CRADA Subject Invention conceived prior to the Effective Date that is first actually reduced to practice in the performance of the Research Plan, the license option offered to Daré in Section 3.8 may be restricted if, before the Effective Date, NIH had filed a Patent Application and had either offered or granted a license in the CRADA Subject Invention to a third party. Daré nonetheless retains the right to apply for a license to any such CRADA Subject Invention in accordance with the terms and procedures of 35 U.S.C. § 209 and 37 C.F.R. Part 404.

4. Data and Materials

4.1 **Obligations when Sharing Confidential Information.** Each Party agrees to limit disclosure of its Confidential Information to the other Party to the amount necessary to conduct the activities of the CRADA. A disclosing party will endeavor to identify both verbal and tangible Confidential Information provided to a receiving party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality if a reasonable person would consider such information to be confidential based on the nature of such information and the circumstances of disclosure.

4.2 **Use of Confidential Information.** Each Party agrees to use the other Party's Confidential Information only for the purpose of conducting the activities of the CRADA. Each Party agrees to use reasonable efforts to maintain the confidentiality of the other Party's Confidential Information, which will in no instance be less effort than the receiving Party uses to protect its own Confidential Information. The Parties may share Confidential Information with their Affiliates, agents, licensees or contractors for the purposes of conducting the Research Plan, provided the obligations of this Article 4 are simultaneously conveyed. No Party will disclose or otherwise make available to any other person or entity another Party's Confidential Information without the consent of that Party, except as required by a court or administrative body of competent jurisdiction, law or regulation. In such a situation, no Party will be liable for the disclosure of that portion of the Confidential Information which, after reasonable notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld. The receiving Party will then provide the disclosing Party a reasonable opportunity to seek a court order to enjoin disclosure. Each Party may retain one (1) copy of the other Party's Confidential Information for archival purposes. Any breach or threatened breach of this CRADA by the receiving Party may entitle the disclosing Party to any remedies in law or equity to which the disclosing Party may be otherwise entitled, in any court of competent jurisdiction.

4.3 **Duration of Confidentiality Obligations.** The obligation to maintain the confidentiality of Confidential Information will expire at the earlier of the date when the information is no longer Confidential Information as defined in Article 2 or [**] after the expiration or termination date of this CRADA. The Parties may negotiate a separate agreement at the end of this period to extend the confidentiality obligation for specific information. The Parties agree not to disclose CRADA Data and descriptions of CRADA Materials until they are made publicly available in accordance with this Article 4. This term does not

apply to ISI, for which the obligation to maintain confidentiality will extend indefinitely, per Section 6.2.

4.4 **Publication.**

a) The Parties are encouraged to make the results of the CRADA research publicly available. Neither Party will publish or publicly disclose any CRADA Data without the other Party's permission until such CRADA Data has been published as permitted in this Section 4.4. The first publication of the results of the Research Plan will be a joint publication that reflects results from all Clinical Research Sites and the Coordinating Center; provided, however, if a publication policy is developed for the Study, then the first publication would be submitted in accordance with that policy.

b) However, if a joint manuscript has not been submitted for publication within [**] of completion or termination of the Study at all participating Clinical Research Sites, or if the NIH Office of General Counsel determines it is in the best interest of the public health, either Party is free to publish CRADA Data separately, subject to any other requirements herein. In such case, the publishing Party will provide the other Party with [**] to review the proposed disclosure to assure that it does not include that Party's Confidential Information. Either Party may request in writing that the disclosure be delayed for [**] as necessary to file a patent application. In the event that including Confidential Information in a publication is required for the publication to go forward, the Party whose Confidential Information is required will work with the other Party in an effort to provide substitute, relevant non-confidential information within [**] of receipt of the draft publication.

4.5 **Right of Access to and Use of CRADA Data.**

a) The Parties agree to exchange all CRADA Data and not to disclose CRADA Data until made publicly available in accordance with this Article 4. The Party that produces CRADA Data will be considered the owner of that CRADA Data. [**] The Parties may share CRADA Data with their Affiliates, agents, and licensees or contractors for purposes relating to the Research Plan provided the relevant obligations of this CRADA are simultaneously conveyed. Any CRADA Data generated by a Clinical Research Site or the Coordinating Center will be owned by the generating entity. NICHD, through its Coordinating Center, will provide Daré with the initial top-line data and ultimately with the entire aggregate clinical data set, in each case within [**].

4.6 **Ownership of CRADA Materials.** The producing Party will retain sole ownership of and title to all CRADA Materials produced solely by its employee(s) ("**Sole CRADA Materials**"), and the Parties will own jointly all CRADA Materials developed jointly ("**Joint CRADA Materials**"). For clarity, the Parties acknowledge that any CRADA Materials produced by one of the Parties and incorporating materials owned by the other Party shall be considered Joint CRADA Materials.

4.7 **Right of Access to and Use of CRADA Materials.** <u>For the activities of the Research Plan</u>: The Parties agree to share all CRADA Materials needed to conduct the activities of the Research Plan. The receiving Party may not use the other Party's CRADA Materials other than as expressly permitted herein. The Parties may share CRADA Materials with

their Affiliates, agents or contractors for the purposes of conducting the activities of the Research Plan provided the obligations of this CRADA convey. Outside the scope of the Research Plan: A producing Party may use or transfer to any third party its Sole CRADA Materials. Upon request, the producing Party will use reasonable efforts to provide reasonable quantities of its Sole CRADA Materials for use by the other Party for internal research only. The Parties acknowledge that any further transfer of Sole CRADA Materials will be at the sole discretion of the owner and may require a separate agreement. Upon request, each Party will provide reasonable quantities of Joint CRADA Materials to another Party if reasonably practicable. Each Party may use Joint CRADA Materials for any purpose provided such use is consistent with any obligations under this CRADA. After public disclosure about Joint CRADA Materials in accordance with this Article 4 and consistent with any obligations under this CRADA, any Party may share Joint CRADA Materials with third parties. However, if a Party shares Joint CRADA Materials with a third party for a commercial purpose, that Party will first inform the other Party.

5. Performance

5.1 **Responsibility of Principal Investigator for Research Plan.** The activities described under the Research Plan of this CRADA will be carried out under the supervision of the Principal Investigators identified on the Summary Page.

5.2 **Consistency of third party obligations.** If Daré has received (or will receive) support of any kind from a third party in exchange for rights in any of Daré's CRADA Subject Inventions, Daré agrees to ensure that its obligations to the third party are consistent with this CRADA.

5.3 **Daré employees at NICHD facilities.** Any Daré employees who will work at NICHD facilities to conduct activities under this CRADA will be required to sign an appropriate agreement in view of the terms of this CRADA.

5.4 **Term and Termination.** This CRADA shall be effective upon the date of last signature of the Parties and will be in force for the term set forth on the Summary Page. The term may be extended and the provisions of this CRADA may be modified only by amendment signed by the duly authorized signatory for each Party. This CRADA may be terminated by either Party for any reason by providing written notice to the other Party at least thirty (30) days prior to the desired termination date. If at the time of such termination, the Study is not complete, then, NICHD will deliver to Daré or its agent all data required under this CRADA, and will cooperate with Daré to transfer the conduct of the Study to Daré or its designee and shall continue to conduct the Study for so long as necessary to enable such transfer to be completed without interruption of the Study.

5.5 **Dispute Resolution.** Any dispute arising under this CRADA which is not disposed of by agreement of the Principal Investigators will be submitted jointly to the signatories of this CRADA. If the signatories, or their designees, are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) will propose a resolution. Nothing in this Section 5.5 will

prevent either Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies. Pending the resolution of any dispute or claim, the Parties agree that performance of all obligations will be pursued diligently.

5.6 **Warranties.** Except as specifically stated herein, the Parties make no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or material, made or developed under or outside the scope of this CRADA, or the ownership, merchantability, or fitness for a particular purpose of the research or any invention or any invention or material, or that a technology utilized by a Party in the performance of the research plan does not infringe any third-party patent rights, and each Party disclaims all such warranties.

5.7 **Indemnification.** No indemnification for any loss, claim, or liability is intended or provided by any Party under this Agreement. Each Party will be liable for any claims or damages it incurs in connection with this CRADA, except that NICHD, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Chapter 171.

5.8 **Force Majeure.** No Party will be liable for any unforeseeable event beyond its reasonable control and not caused by its own fault or negligence, which causes the Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. If a *force majeure* event occurs, the Party unable to perform will promptly notify the other Party. It will use its best efforts to resume performance as quickly as possible and will suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

5.9 **Third Party Contractor Obligations.** The Study will be conducted by Clinical Research Sites and a Coordinating Center, which are contractors or subcontractors of NICHD. As noted in Section 3.1, Daré acknowledges that it is aware that under the Bayh-Dole Act (35 U.S.C. Part 2, Chapter 19) that these third parties may retain title to any Invention each third party makes in the performance of its duties despite the fact that the Government supported the work, and consequently, NICHD has no authority to make such an Invention subject to the terms of this CRADA. However, Daré may enter into a separate agreement with a third party regarding any issue, provided however that the separate agreement does not contradict the terms of this CRADA or the third party's contract or subcontract with NICHD.

5.10 **Debarment.** To the best of its knowledge and belief, neither NICHD nor any individuals working on behalf of NICHD involved in this CRADA is presently subject to debarment or suspension by any agency of the Government. Should NICHD or any individuals working on behalf of NICHD in this CRADA be debarred or suspended during the term of this CRADA, NICHD will notify Daré within thirty (30) days of receipt of final notice. To the best of its knowledge and belief, neither Daré nor any individuals working on behalf of Daré involved in this CRADA, including Affiliates, agents, and contractors are presently subject to debarment or suspension by any agency of the Government. Should Daré or any individuals working on behalf of Daré involved in this CRADA be debarred

or suspended during the term of this CRADA, Daré will notify NICHD within thirty (30) days of receipt of final notice.

5.11 **CRADA Funding.** Daré will provide funds in accordance with the payment schedule in this Section 5.11. If Daré fails to make any scheduled payment, NICHD will not be obligated to carry out research and development activities until funds have been received. Daré agrees to provide funds in four payments in support of the CRADA for NICHD's use [**]. The funding schedule is as follows:

Payment 1: within thirty (30) days of the Effective Date, $250,000 (Two Hundred and Fifty Thousand Dollars);

Payment 2: due by [**], 2021, $1,250,000 (One Million Two Hundred and Fifty Thousand Dollars);

Payment 3: due by [**], 2022, $3,500,000 (Three Million Five Hundred Thousand Dollars);

Payment 4: due by April 1, 2023, $500,000 (Five Hundred Thousand Dollars)

[**]

[**]

Daré acknowledges that NICHD may retain and use any funds for up to one (1) year after expiration or termination to cover costs associated with the conduct of activities described under the Research Plan that were initiated prior to expiration or termination or as needed per Section 6.6(d), and NICHD will promptly return any remainder to Daré.

5.12 **Limitations of CRADA Funding.**

a) The Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a(d)(1) prohibits NICHD from providing funds to Daré to conduct any activities described in the Research Plan under this CRADA.

b) NICHD will not use funds provided by Daré under this CRADA for NICHD personnel to pay the salary of any permanent NICHD employee. No NICHD employees will be required to devote 100% of their effort or time to performance of the Research Plan.

5.13 **CRADA Reporting Requirements.** The PIs should exchange information regularly, as required to advance the activities under the Research Plan. NICHD, through its Coordinating Center, will deliver to Daré the final clinical study report of the results within [**] of the database lock by the Coordinating Center that will occur after completion of the pivotal study portion of the Research Plan, even in the event of termination of this Agreement.

5.14 **CRADA Subject Inventions Reporting Requirements**. NICHD will deliver to Daré the final CRADA Subject Inventions, and corresponding patent applications arising from the activities under the Research Plan, within [**] of completion of the Research Plan.

6. Clinical

6.1 **Handling of Human Specimens.** All specimens from Human Subjects related to the activities under the Research Plan must be handled as described in the Protocol including return or disposal of specimens from Human Subjects when the Protocol(s) is terminated or completed. CRADA Materials do not include human specimens.

6.2 **Confidentiality of ISI.**

a) Each Party agrees to limit its disclosure of its Confidential Information to the amount reasonably necessary to carry out the CRADA activities. Identifiable Sensitive Information shall be treated as confidential in accordance with the terms of this CRADA. While ISI is not considered to be Confidential Information, the Parties agree to maintain the confidentiality of ISI indefinitely.

b) **Certificate of Confidentiality Obligations.** Any ISI that Daré receives from NIH is covered by a CoC and therefore all copies of ISI are immune from the legal process, and will not, without the consent of the Human Subject, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

Notwithstanding the forgoing, Daré will be permitted to disclose ISI:

i. If required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

ii. If the consent of the Human Subject to whom the information, document, or biospecimen pertains obtained by the NICHD allowed for such disclosure.

Prior to making any permitted disclosures above, Daré will ensure that any recipient of ISI protected by a CoC is aware of its confidential nature and the requirement to comply with the CoC (see https://humansubjects.nih.gov/coc/background).

6.3 **Applicable Law for Human Subject Research.** Each Party agrees that they will comply with, and advise their contractors and agents to comply with, all applicable statutes, Executive Orders, HHS regulations, and all FDA, CDC, and NIH policies relating to research on Human Subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56). Also, the Parties will advise any contractors, grantees, or agents engaged to conduct activities under this CRADA to comply with all applicable Executive Orders, statutes, and HHS regulations, which may also include 45 C.F.R. Parts 160, 162, and 164 (Health Insurance Portability and Accountability Act regulations for privacy and security of individual health information).

6.4 **Protocol Review.** A single IRB will be utilized for the Study. Each Clinical Research Site will enter into a reliance agreement with the single IRB. In addition to the Protocol, all associated documents, including informational documents and advertisements, must be reviewed and approved by the single IRB before starting the research at each Clinical Research Site. The research will be done in strict accordance with the Protocol and no changes in a finalized Protocol will be made unless mutually agreed upon, in writing, by the Parties. Research will not commence or will continue unchanged (if already in progress) until each change to a Protocol, including those required by either the FDA or the IRB, has been integrated in a way acceptable to the Parties, submitted to the FDA (if applicable) and approved by the single IRB.

6.5 **Daré Sponsored Studies outside of CRADA.** Daré may sponsor its own clinical trials and hold its own IDE for studies performed outside the scope of this CRADA. All data from such clinical trials are proprietary to Daré for purposes of this CRADA.

6.6 **Test Article.**

a) Daré agrees to provide NICHD without charge and on a schedule that will ensure adequate and timely performance of the activities under the Research Plan, a sufficient quantity of Test Article to support conduct of the Protocol. Daré will provide NICHD with documentation verifying the validation of the provided Test Article. NICHD, through the Coordinating Center, will provide Daré with updated forecasts of amounts of Test Article anticipated for the Study on a mutually agreeable schedule.

b) Daré will ship the Test Article to the Coordinating Center’s designated distribution site for distribution to the Clinical Research Sites. NICHD agrees that the Test Article will be used solely for the activities under the Research Plan. At the completion of the Research Plan, any unused quantity of Test Article will be returned to Daré or disposed of as directed by Daré.

c) Daré warrants that the Test Article provided has been produced in accordance with the FDA's Current Good Manufacturing Practice for Combination Products set out in 21 C.F.R. Part 4, and meets the specifications cited in the Investigator's Brochure. Daré will provide the Investigator’s Brochure (and all subsequent revisions or editions) to the Coordinating Center for distribution to the Clinical Research Sites.

d) If Dare terminates this CRADA before the completion of any active Protocol, then Daré will supply enough Test Article for NICHD to complete the Protocol unless termination is for safety concerns.

6.7 **Interactions with the FDA.** All meetings with the FDA concerning any Protocol or Study within the scope of the Research Plan will be discussed by the Parties in advance. [**], *provided, however*, that Daré shall have the sole and exclusive right to control and make all determinations with respect to the agenda. The IDE Sponsor (Daré) will provide the other Party with copies of FDA meeting minutes, all transmittal letters for IDE submissions, IDE safety reports, Investigator's Brochure, preclinical data, toxicology

filings, formal questions and responses that have been submitted to the FDA, progress reports, and official FDA correspondence, pertaining either to the IDEs under this CRADA or to the Clinical Investigators on Protocols performed in accordance with the activities under the Research Plan, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law, and *provided, however*, that, as between the Parties, Daré shall have the sole and exclusive right to submit all written communications and submissions to the FDA.

6.8 **IDE Sponsor.**

a) Daré will use commercially reasonable efforts to submit an IDE to the FDA and NIHCD will ensure that all Clinical Investigators must have completed registration documents on file (1572 forms).

b) If NICHD supplies Confidential Information to Daré in support of an IDE filed by Daré, this information will be protected in accordance with the corresponding confidentiality provisions of this CRADA.

c) Subject to the restrictions concerning ISI, and with reasonable advance notice and at reasonable times, NICHD will permit Daré or its designee(s) access to Clinical Research Site(s) to monitor or audit the conduct of the research, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with FDA Good Clinical practice and the Protocol(s). For clarity, Daré should not monitor a Clinical Research Site unless a specific request was made by Daré to NICHD and NICHD granted permission for such activity.

d) In accordance with FDA requirements, the IDE Sponsor will establish and maintain records and submit safety reports to the FDA, as required by 21 C.F.R. § 812.150(b)(1), or other applicable regulations. The Parties will comply with procedures specified in the Protocol(s).

e) During and for a period of two years after the completion of a Protocol, Daré shall promptly provide to NICHD any information that Daré has reasonably determined could directly affect the health or safety of past or current Human Subjects or influence the conduct of the Protocol. Such information may arise from any source, for example, Safety Reports provided to the FDA, study results, information in site monitoring reports or data safety monitoring committee reports. NICHD shall be free to communicate the relevant safety information to each Human Subject and the IRB.

6.9 **Daré Sponsored Studies outside of CRADA.** Daré may sponsor its own clinical trials and hold its own IDE for studies performed outside the scope of this CRADA. All data from such clinical trials are proprietary to Daré for purposes of this CRADA.

7. Miscellaneous

7.1 **Governing Law.** The construction, validity, performance and effect of this CRADA will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this CRADA conflicts with or is inconsistent with any

U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.

7.2 **Waiver of CRADA Provisions.** None of the provisions of this CRADA will be considered waived by any Party unless given in writing to the other Party.

7.3 **Amendments to the CRADA.** Modifications to the Research Plan may be made by the mutual written consent of the Parties; *provided, however,* that Daré may amend the Research Plan without NIHCD consent as necessary to comply with applicable law. Any changes to the CRADA will become effective only upon a written, fully executed amendment.

7.4 **Assignment of CRADA.** Neither this CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by any Party without the prior written consent of the other Party. Daré acknowledges the applicability of 41 U.S.C. § 15, the Anti-Assignment Act, to this CRADA. The Parties agree that the identity of Daré is material to the performance of this CRADA and that the duties under this CRADA are nondelegable.

7.5 **Relationship of Parties under the CRADA.** The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Both Parties will maintain sole and exclusive control over their personnel and operations.

7.6 **Endorsement.** By entering into this CRADA, the Government does not directly or indirectly endorse any product or service. Daré will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or service.

7.7 **Press Releases.** Each Party agrees to provide proposed press releases that reference or rely upon the work under this CRADA to the other Party for review and comment [**] prior to publication. For the avoidance of doubt, Daré may publicly disclose the existence of this CRADA, the financial terms of this CRADA, and may publicly identify NICHD as carrying out the Study, consistent with Section 7.6.

7.8 **Consent.** Whenever a Party's consent or permission is required under this CRADA, its consent or permission will not be unreasonably withheld. Regarding a jointly owned CRADA Subject Invention, if Daré decides not to take a commercial license from NICHD and seeks to grant one or more commercial licenses to third parties independently, NICHD shall have the right to withhold consent for any reason to the extent permitted by the applicable laws of the countries covered by the proposed license. Daré may withhold consent for NICHD granting a commercial license to a third party: (a) only if Daré submits a new and complete license application under 37 CFR Part 404 and negotiates such commercial license in good faith, and (b) only to the extent permitted by the applicable laws of the countries covered by the license proposed by Daré.

7.9 **Export Compliance.** Daré agrees to comply with U.S. export law and regulations. If required, Daré will acquire any and all necessary export licenses and other appropriate authorizations.

7.10 **CRADA Travel Payments**. Travel arrangements for all Government staff will be made in accordance with the Federal Travel Rules and Regulations, whether arranged by NICHD and funded using either appropriated funds or CRADA funds, or arranged and funded directly by Daré.

7.11 **Superseding of Prior Agreements.** Specifically, the Confidential Disclosure Agreement executed by the Parties on [**], is hereby superseded and succeeded by the terms of this CRADA. The confidential information exchanged between the Parties under that agreement shall be governed by the terms of this CRADA as if the information had been exchanged after execution of this CRADA, and not under the terms of the prior agreement.

7.12 **In Case of Breach.** Any breach or threatened breach of this CRADA may entitle any Party to any remedies in law or equity to which the Party may be otherwise entitled, in any court of competent jurisdiction.

7.13 **Survivability.** The provisions of Article 3 and 4, and Sections 5.2, 5.5 - 5.9, 6.1, 6.2, 6.4, 6.6 – 6.8, 7.1, 7.2, 7.6, 7.8, and 7.13 will survive the expiration or early termination of this CRADA.

SIGNATURES ON THE NEXT PAGE

SIGNATURE PAGE

ACCEPTED AND AGREED

By executing this crada, each Party represents that all statements made herein are true, complete, and accurate to the best of its knowledge. Daré acknowledges that it may be subject to criminal, civil, or administrative penalties for knowingly making a false, fictitious, or fraudulent statement or claim.

FOR **NICHD**

/s/ Christopher J. Mcbain 2021.07.08

_____ _____

Chris J. McBain, Ph.D. Date
Acting Scientific Director

FOR **DARÉ BIOSCIENCE, INC.**

/s/ Sabrina Martucci Johnson July 8, 2021

_____ _____

Sabrina Martucci Johnson Date
President and CEO

SUMMARY PAGE

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION, RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

TITLE OF CRADA:
Pivotal Phase III Study to Evaluate the Effectiveness of Ovaprene® as a Contraceptive Device

NIH Institute, Center, or Division:	NICHD
NICHD CRADA Principal Investigator:	Diana Blithe, PhD
Collaborator:	Daré Bioscience, Inc.
Daré CRADA Principal Investigator:	Christine Mauck, MD, MPH
Term of CRADA:	Five (5) years from the Effective Date

ABSTRACT OF THE RESEARCH PLAN:

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and Daré Bioscience, Inc., will conduct a Phase III pivotal study under this Cooperative Research and Development Agreement. Daré will provide its investigational contraceptive device, Ovaprene®, for the pivotal study, which will be conducted in NICHD's multi-center Contraceptive Clinical Trials Network to evaluate the effectiveness of Ovaprene®.

Exhibit 31.1

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 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: November 10, 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 September 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: November 10, 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 September 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: November 10, 2021

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