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, 2020

OR

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

For the transition period from _____ to _____

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

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

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

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

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

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

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

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

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

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

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

As of November 11, 2020, 37,990,001 shares of the Registrant's Common Stock, par value $0.0001, were issued and outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, in particular "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," of Part I. Financial Information, and the information incorporated by reference herein contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," project," "target," "tend to," or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors described in Part II, Item 1A, "Risk Factors," in this report, and elsewhere in this report. Given these uncertainties, you should not place undue reliance on any forward-looking statement. The following factors are among those that may cause such differences:

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

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

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

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

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

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 5,389,414	$ 4,780,107
Other receivables	213,560	555,210
Prepaid expenses	1,381,462	1,108,615
Total current assets	6,984,436	6,443,932
Property and equipment, net	42,349	63,531
Other non-current assets	634,957	935,325
Total assets	$ 7,661,742	$ 7,442,788
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 1,555,307	$ 1,083,183
Accrued expenses	2,454,048	2,098,653
Deferred grant funding	2,178,379	2,019,674
Note payable	367,285	—
Current portion of contingent consideration	1,000,000	—
Current portion of lease liabilities	409,647	410,896
Total current liabilities	7,964,666	5,612,406
Deferred license revenue	1,000,000	—
Contingent consideration, net of current portion	—	1,000,000
Lease liabilities long-term	82,964	389,556
Total liabilities	9,047,630	7,001,962
Commitments and contingencies (Note 8)		
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; 33,602,516 and 19,683,401 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	3,360	1,968
Accumulated other comprehensive loss	(112,807)	(102,625)
Additional paid-in capital	61,712,882	44,564,674
Accumulated deficit	(62,989,323)	(44,023,191)
Total stockholders' equity (deficit)	(1,385,888)	440,826
Total liabilities and stockholders' equity (deficit)	$ 7,661,742	$ 7,442,788

See accompanying notes to interim consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses				
General and administrative	$ 1,353,069	$ 1,318,986	$ 4,772,382	$ 3,903,545
Research and development	6,203,753	1,966,230	14,131,007	6,172,192
License fees	25,000	133,333	58,333	408,333
Total operating expenses	7,581,822	3,418,549	18,961,722	10,484,070
Loss from operations	(7,581,822)	(3,418,549)	(18,961,722)	(10,484,070)
Other income (expense)	(986)	25,471	2,454	86,703
Net loss	$ (7,582,808)	$ (3,393,078)	$ (18,959,268)	$ (10,397,367)
Deemed dividend from trigger of down round provision feature	(6,863)	—	(6,863)	(789,594)
Net loss to common shareholders	$ (7,589,671)	$ (3,393,078)	$ (18,966,131)	$ (11,186,961)
Foreign currency translation adjustments	672	(15,378)	(10,182)	(15,674)
Comprehensive loss	$ (7,588,999)	$ (3,408,456)	$ (18,976,313)	$ (11,202,635)
Loss per common share - basic and diluted	$ (0.24)	$ (0.20)	$ (0.69)	$ (0.76)
Weighted average number of common shares outstanding:				
Basic and diluted	31,588,152	16,683,411	27,381,508	14,756,213

See accompanying notes to interim consolidated financial statements.

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

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

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2018	**11,422,161**	**$ 1,143**	**$ 35,791,972**	**$ (96,728)**	**$ (28,969,767)**	**$ 6,726,620**
Stock-based compensation	—	—	97,968	—	—	97,968
Net loss	—	—	—	—	(3,051,840)	(3,051,840)
Foreign currency translation adjustments	—	—	—	7,621	—	7,621
Balance at March 31, 2019	**11,422,161**	**$ 1,143**	**$ 35,889,940**	**$ (89,107)**	**$ (32,021,607)**	**$ 3,780,369**
Stock-based compensation	—	—	111,351	—	—	111,351
Issuance of common stock via public offering, net	5,261,250	525	5,151,177	—	—	5,151,702
Deemed dividend from trigger of down round provision	—	—	789,594	—	(789,594)	—
Net loss	—	—	—	—	(3,952,450)	(3,952,450)
Foreign currency translation adjustments	—	—	—	(7,917)	—	(7,917)
Balance at June 30, 2019	**16,683,411**	**$ 1,668**	**$ 41,942,062**	**$ (97,024)**	**$ (36,763,651)**	**$ 5,083,055**
Stock-based compensation	—	—	135,393	—	—	135,393
Net loss	—	—	—	—	(3,393,078)	(3,393,078)
Foreign currency translation adjustments	—	—	—	(15,378)	—	(15,378)
Balance at September 30, 2019	**16,683,411**	**$ 1,668**	**$ 42,077,455**	**$ (112,402)**	**$ (40,156,729)**	**$ 1,809,992**

See accompanying notes to interim consolidated financial statements.

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

	Nine months ended September 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (18,959,268)	$ (10,397,367)
Non-cash adjustments reconciling net loss to operating cash flows:		
Depreciation	36,428	3,491
Stock-based compensation	542,582	344,712
Non-cash operating lease cost	(125,517)	(19,914)
Changes in operating assets and liabilities:		
Other receivables	341,650	(6,802)
Prepaid expenses	18,682	(367,409)
Other non-current assets	118,044	138,719
Accounts payable	472,124	(107,463)
Accrued expenses	355,395	905,236
Deferred grant funding	158,704	—
Deferred license revenue	1,000,000	—
Net cash used in operating activities	(16,041,176)	(9,506,797)
Investing activities:		
Purchases of property and equipment	(15,246)	—
Net cash used in investing activities	(15,246)	—
Financing activities:		
Net proceeds from issuance of common stock	14,522,645	5,151,702
Proceeds from the exercise of common stock warrants	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	16,675,911	5,151,702
Effect of exchange rate changes on cash and cash equivalents	(10,182)	(15,674)
Net change in cash and cash equivalents	609,307	(4,370,769)
Cash and cash equivalents, beginning of period	4,780,107	6,805,889
Cash and cash equivalents, end of period	$ 5,389,414	$ 2,435,120
Supplemental disclosure of non-cash operating and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 231,698
Issuance cost on equity paid in common stock	$ 291,428	$ —
Deemed dividend from trigger of down round provision feature	$ 6,863	$ 789,594

See accompanying notes to interim consolidated financial statements.

1. ORGANIZATION AND DESCRIPTION OF THE BUSINESS

Daré Bioscience, Inc. is a clinical-stage biopharmaceutical company committed to the acceleration of 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, acquire and develop a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, fertility, and sexual and vaginal 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. While the Company will continue to assess opportunities to expand its portfolio, its current focus is on advancing its existing product candidates through mid- and late-stages of clinical development or approval. The Company's portfolio includes three product candidates in advanced clinical development:

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis;
- **Ovaprene®**, a hormone-free, monthly vaginal 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 the Company believes are Phase 1-ready:

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring for the treatment of menopausal symptoms, including vasomotor symptoms, as part of a hormone replacement therapy, or HRT, 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, or VVA, in patients with hormone-receptor positive breast cancer.

The Company's portfolio also includes these pre-clinical stage product candidates:

- **DARE-LARC1**, a combination product designed to provide long-acting, reversible contraception comprising an implantable, user-controlled wireless drug delivery system and levonorgestrel;
- **ORB-204 and ORB-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 of, product research and development and advancing its portfolio of product candidates through clinical development and regulatory approval. The Company expects that the majority of its development expenses for the remainder of 2020 and in 2021 will support 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 product revenue. The Company is subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key employees as well as third-party licensors, partners 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, dependence on third parties, and product liability.

Going Concern

The Company has prepared its interim 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 operations will continue for the foreseeable future, and expects that its net losses will continue for at least the next several years as it develops its existing product candidates and seeks to acquire, license or develop additional product candidates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification 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, 2020, the Company had an accumulated deficit of approximately $63.0 million and cash and cash equivalents of approximately $5.4 million. The Company also had negative cash flow from operations of approximately $16.0 million during the nine months ended September 30, 2020.

The Company is focused primarily on the development and commercialization of innovative products in women’s health. The Company will continue to incur significant research and development and other expenses related to these activities. If the clinical trials for any of the Company’s product candidates fail to produce successful results such that those product candidates do not advance in clinical development, then the Company’s business and prospects may suffer. Even if the product candidates advance in clinical development, they may fail to gain regulatory approval. Even if the product candidates are approved, they may fail to achieve market acceptance, and the Company may never become profitable. Even if the Company becomes profitable, it may not sustain profitability.

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 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 to continue the planned development of DARE-BV1, Ovaprene, and Sildenafil Cream, 3.6%.

The Company is currently evaluating a variety of capital raising options, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover its operating expenses, including the development of its product candidates and any future product candidates it may license or otherwise acquire. The amount and timing of the Company's capital needs have been and will continue to depend highly on many factors, including the product development programs the Company chooses to pursue and the pace and results of its clinical development efforts. If the Company raises capital through collaborations, strategic alliances or other similar types of arrangements, it may have to relinquish, on terms that are not favorable to the Company, rights to some of its technologies or product candidates it would otherwise seek to develop or commercialize. There can be no assurances that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders. Additionally, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will not be able to continue development of its product candidates, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If the Company becomes unable to continue as a going concern, the Company may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its consolidated financial statements, and stockholders may lose all or part of their investment in the Company's common stock. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The effect of the COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain a rapidly evolving and uncertain risk to the Company's business, operating results, financial condition and stock price. In large part, the extent to which the pandemic affects the Company will depend on future developments that are beyond its 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 or facilitate development of or access to therapies to treat or vaccinations to protect against the disease, governmental actions and policies to assist economic recovery, and the speed with which and degree to which normal economic and operating conditions resume. Infectious disease experts have cautioned that the U.S. may experience a substantial surge in cases and hospitalizations during the cooler months, which may lead the federal government and/or state governments to impose or re-impose stay-at-home orders and shutdowns of non-essential businesses in efforts to reduce the spread of the disease, such as those announced by the United Kingdom, Germany, France and other European countries in October 2020. The pandemic may increase the anticipated aggregate costs for the development of the Company's product candidates and may adversely impact the anticipated timelines for the development of the Company's product candidates by, among other things, causing disruptions in the supply chain for clinical supplies, delays in the commencement of clinical trials, delays in the timing and pace of subject enrollment in any ongoing clinical trials and lower than anticipated subject enrollment and completion rates, delays in the review and approval of the Company's regulatory submissions by regulatory agencies with respect to the Company's product candidates, and other unforeseen disruptions. The economic impact of the pandemic and the uncertainty and volatility in the capital markets it has caused, and may continue to cause, may negatively impact investor sentiment and the availability and cost of capital, and may adversely impact the Company's ability to raise capital when needed or on terms favorable to the Company and its stockholders to fund its development programs and operations. Given the high level of uncertainty regarding the duration and impact of the COVID-19 pandemic on the U.S. and global economies, workplace environments and capital markets, the Company is unable to assess the impact of the pandemic on its operations. The full extent to which the COVID-19 pandemic will impact the Company's business, results of operations, financial condition, clinical trials, and preclinical research and access to capital will depend on future developments that are highly uncertain.

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, 2019, filed with the Securities and Exchange Commission, or SEC on March 27, 2020. Since the date of those consolidated financial statements, there have been no material changes to the Company’s significant accounting policies, except for the accounting policies related to revenue recognition as described below.

Basis of Presentation

The accompanying interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, as defined by the Financial Accounting Standards Board, or FASB, for interim financial information and 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 interim 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 interim consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use, or ROU, lease assets, current portion of lease obligations, and long-term lease obligations on the Company's consolidated balance sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date based on the present value of lease payments over the lease term. If the lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease asset 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 7, Leased Properties.)

Fair Value Measurements

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, 2020 and December 31, 2019. 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, 2020.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at September 30, 2020				
Current assets:				
Cash and cash equivalents	$ 5,389,414	$ —	$ —	$ 5,389,414
Current liabilities:				
Current portion of contingent consideration	$ —	$ —	$ 1,000,000	$ 1,000,000
Balance at December 31, 2019				
Current assets:				
Cash and cash equivalents	$ 4,780,107	$ —	$ —	$ 4,780,107
Other non-current liabilities:				
Contingent consideration, net of current portion	$ —	$ —	$ 1,000,000	$ 1,000,000

Revenue Recognition

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

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

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

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

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 resulting from any of its collaborative arrangements.

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, 2020, neither of the foregoing had occurred. The $1.0 million payment is recorded as long term deferred revenue in the Company's consolidated balance sheet at September 30, 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, and (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

On January 10, 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, including the first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

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 to 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, an antibiotic with FDA approval to treat certain bacterial infections, including bacterial vaginosis. In December 2019, the Company entered into amendments to each of the License Amendment and Assignment Agreement.

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

License Fees. The Company paid MilanaPharm: (1) $25,000 in connection with the execution of the License Amendment; (2) $100,000 on December 5, 2019; and (3) $110,000 on January 31, 2020.

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

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. After the commercial launch of licensed products and processes and 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 in accordance with the agreement.

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 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 (or process) 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 in favor of all parties, MilanaPharm may terminate the license solely with respect to a licensed product or process in a country if, after having launched such product or process in such country, the Company or its affiliates or sublicensees, (1) 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) (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. The Company paid Hammock: (1) $250,000 in connection with the execution of the Assignment Agreement; (2) $125,000 on December 5, 2019; and (3) $137,500 on January 31, 2020.

Milestone Payments. The Company will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $100,000 of which was paid during the third quarter of 2020.

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.

Milestone Payments. The Company will pay 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 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 (1) the Company develops or commercializes any non-hormonal ring-based vaginal contraceptive device competitive to Ovaprene or (2) if the Company fails to meet agreed upon efforts to commercialize Ovaprene.

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 the Licensed Product (as defined below), in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, or the Field of Use. The Licensed Product, is defined as SST's proprietary topical formulation of sildenafil cream 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.

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 will 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 upon 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.

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 was $50,000 for each of the first two years and will be $100,000 thereafter, and which will be creditable against royalties and other payments due to Catalent in the same calendar year but may not be carried forward to any other year.

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

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.

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 (ORB-204 and ORB-214, respectively). Under this agreement, the Company paid Adare $300,000 to conduct the first stage of development work 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 September 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 January 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 ORB-204 and ORB-214 should development efforts be successful.

Acquired Products

Microchips Acquisition

As further discussed in Note 4. Acquisition below, in November 2019, the Company completed its acquisition of Microchips (as defined below). The Company acquired Microchips to secure the rights to develop an implantable, user-controlled, long-acting reversible contraception method, now known as DARE-LARC1. The Company agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to the implantable contraceptive product in development by Microchips.

The Company issued an aggregate of 2,999,990 shares of its common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger.

The Company also agreed to pay the following contingent consideration to the former Microchips 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. The Company recorded $1.0 million in contingent consideration associated with milestone payments it expects to become payable in the first half of 2021.

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. ACQUISITION

In November 2019, the Company acquired Microchips Biotech, Inc., or Microchips, via a merger transaction in which a wholly owned subsidiary of the Company, formed for purposes of this transaction, merged with and into Microchips, and Microchips survived as the Company's wholly owned subsidiary. Microchips is developing a proprietary, implantable drug delivery system designed to store and precisely deliver numerous therapeutic doses over months and years on a schedule determined by the user and controlled via wireless remote. Microchips' lead product candidate is a pre-clinical stage contraceptive application of that technology that utilizes levonorgestrel, 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 Microchips' 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 of $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 Microchips' 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 certain contingent consideration payments, tiered royalty payments and a percentage of sublicense revenue as discussed in Note 3, Acquired Products—Microchips Acquisition, above.

The Company determined the transaction was accounted for as an asset acquisition as there were no outputs or substantive processes in existence as of the acquisition date. Transaction costs of approximately $202,000 associated with the merger were included in the Company's research and development expense in the fourth quarter of 2019.

5. STOCK-BASED COMPENSATION

The 2015 Employee, Director and Consultant Equity Incentive Plan

In connection with the business combination transaction in July 2017 between the Company and Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, the Company assumed the Private Daré 2015 Employee, Director and Consultant Equity Incentive Plan, or the 2015 Private Daré Plan and each then outstanding award granted thereunder, which consisted of options and restricted stock. Based on the exchange ratio for the business combination transaction and after giving effect to the reverse stock split effected in connection with the closing of that transaction, the outstanding options and restricted stock awards granted under the 2015 Private Daré Plan were replaced with options to purchase 10,149 shares of the Company's common stock with a correspondingly adjusted exercise price and 223,295 shares of the Company's common stock. All of the options that were assumed were exercised as of September 30, 2020. No awards may be granted under the 2015 Private Daré Plan following the closing of the business combination transaction.

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 and there was no stock-based compensation related to the ESPP for the nine months ended September 30, 2020 or September 30, 2019.

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, 2020, the number of authorized shares increased by 787,336 to 1,411,481, 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, 2020. The exercise price of all options granted during the nine months ended September 30, 2020 was equal to the market value of the Company's common stock on the date of grant. As of September 30, 2020, unamortized stock-based compensation expense of $1,493,686 will be amortized over a weighted average period of 2.37 years. At September 30, 2020, 507,516 shares of common stock were reserved for future awards granted under the Amended 2014 Plan.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2019	1,889,775	$ 1.21
Granted	903,965	1.06
Exercised	(10,149)	0.01
Canceled/forfeited	—	—
Expired	—	—
Outstanding at September 30, 2020	2,783,591	$ 1.16
Exercisable at September 30, 2020	1,038,659	$ 1.48

Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 60,546	$ 27,081	$ 166,639	$ 78,780
General and administrative	$ 134,336	$ 108,312	$ 375,943	$ 265,932
Total	$ 194,882	$ 135,393	$ 542,582	$ 344,712

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, 2020 are as follows:

	Three Months Ended September 30,	Nine Months Ended September 30,
Expected life in years	10.0	10.0
Risk-free interest rate	0.71%	0.82%
Expected volatility	119%	120%
Forfeiture rate	0.0%	0.0%
Dividend yield	0.0%	0.0%
Weighted-average fair value of options granted	$1.10	$1.00

6. STOCKHOLDERS' EQUITY

ATM Sales Agreement

In January 2018, the Company entered into a common stock sales agreement under which the Company may sell shares of its common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company will pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement plus certain legal expenses. The common stock sales agreement was amended in August 2018 to refer to the Company's shelf registration statement on Form S-3 (File No. 333-227019) that was filed to replace the Company's shelf registration statement on Form S-3 (File No. 333-206396) that expired on August 28, 2018.

During the three months ended September 30, 2020, the Company sold 1,952,512 shares under the common stock sales agreement for gross proceeds of approximately $2.4 million and incurred offering expenses of approximately $82,000. During the nine months ended September 30, 2020, the Company sold 7,916,092 shares under the common stock sales agreement for gross proceeds of approximately $10.8 million and incurred offering expenses of approximately $420,000. The Company did not sell any shares under this agreement during the three or nine months ended September 30, 2019.

April 2019 Underwritten Public Offering

In April 2019, the Company closed an underwritten public offering of 4,575,000 shares of its common stock at a public offering price of $1.10 per share. The Company granted the underwriters a 30-day over-allotment option to purchase up to an additional 686,250 shares which was exercised in full on April 12, 2019. Including the over-allotment shares, the Company issued a total of 5,261,250 shares in the underwritten public offering and received gross proceeds of approximately $5.8 million and net proceeds of approximately $5.2 million after deducting underwriting discounts and offering expenses.

Equity Line

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

The Company incurred legal, accounting, and other fees related to the Purchase Agreement of approximately $374,000. These costs are amortized and expensed as shares are sold under the Purchase Agreement and as of September 30, 2020 there was approximately $269,000 of unamortized costs. During the three months ended September 30, 2020, the Company sold, and Lincoln Park purchased, 3.0 million shares under the Purchase Agreement for gross proceeds of approximately $3.3 million and incurred offering expenses of approximately $83,000. During the nine months ended September 30, 2020, the Company sold, and Lincoln Park purchased, 3,882,160 shares under the Purchase Agreement for gross proceeds of approximately $4.2 million and incurred offering expenses of approximately $105,000.

Under the Purchase Agreement, on any business day until May 19, 2023, the Company may direct Lincoln Park to purchase up to 200,000 shares of common stock, each, a Regular Purchase. The Company may increase the share amount it directs Lincoln Park to purchase under a Regular Purchase to up to 250,000 shares or up to 300,000 shares if the closing sale price of the Company's common stock is not below $1.50 or $3.00, respectively, on the business day on which the Company initiates the purchase, subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction as provided in the Purchase Agreement. However, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1.0 million. The purchase price per share for each Regular Purchase will be the lower of (i) the lowest sale price of the Company's common stock on the business day on which the Company initiates the purchase and (ii) the average of the three lowest closing sale prices of the Company's common stock during the 10-business day period immediately preceding the business day on which the Company initiates the purchase. In addition to Regular Purchases, the Company may also direct Lincoln Park to purchase other amounts of common stock as accelerated purchases and as additional accelerated purchases, subject to limits specified in the Purchase Agreement, at a purchase price per share calculated as specified in the Purchase Agreement, but in no case lower than the minimum price per share the Company stipulates in its notice to Lincoln Park initiating these purchases.

In addition, under applicable Nasdaq rules, the Company may not issue or sell to Lincoln Park under the Purchase Agreement more than 4,941,089 shares of its common stock, or the Exchange Cap, unless (i) the Company obtains stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of the Company's common stock to Lincoln Park under the Purchase Agreement equals or exceeds $1.0117 (which represents the closing sale price per share of the Company's common stock on the day before the Company entered into the Purchase Agreement, plus an incremental amount). In addition, the Company may not sell shares to Lincoln Park under the Purchase Agreement if such sale would result in Lincoln Park beneficially owning more than 9.99% of the Company's then outstanding shares of common stock.

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 that initially had an exercise price of $3.00 per share and are exercisable through February 2023. 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 has been 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 three months ended September 30, 2020, warrants to purchase an aggregate of 126,000 shares of common stock were exercised for gross proceeds of approximately $121,000. 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. No warrants were exercised during the three or nine months ended September 30, 2019. As of September 30, 2020, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
2,906	$	120.40	2021-12-01
3,737	$	120.40	2021-12-06
6,500	$	10.00	2026-04-04
1,895,500	$	0.96	2023-02-15
1,908,643			

7. LEASED PROPERTIES

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018 and terminates on July 31, 2021. The Company has the option to extend the term of the lease for one year.

Microchips, which 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 and terminates on September 30, 2021. 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. The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At September 30, 2020, the Company reported operating lease ROU assets of approximately $306,000 in other non-current assets, and $410,000 and $83,000, respectively, in current and non-current other liabilities on the consolidated balance sheet.

Total operating lease costs were approximately $76,000 and $27,000 for the three months ended September 30, 2020 and September 30, 2019, respectively, and $228,000 and $81,000 for the nine months ended September 30, 2020 and September 30, 2019, 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 consolidated statement of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were approximately $111,000 and $28,000 for the three months ended September 30, 2020 and September 30, 2019, respectively, and $349,000 and $81,000 for the nine months ended September 30, 2020 and September 30, 2019, respectively. These amounts are included in operating activities in the consolidated statements of cash flows. Further, at September 30, 2020, operating leases had a weighted average remaining lease term of 1.14 years.

As of September 30, 2020, future minimum payments under the Company's operating leases are approximately:

Remainder of 2020	$	112,000
2021		363,000
2022		42,000
Total future minimum lease payments		517,000
Less: Difference between future minimum lease payments and discounted operating lease liabilities		24,000
Total operating lease liabilities	$	493,000

8. COMMITMENTS AND CONTINGENCIES

Contingent Consideration

In connection with the acquisition of Microchips, the Company agreed to pay contingent consideration based upon the achievement of specified funding, product development and regulatory milestones. The Company recorded $1.0 million in contingent consideration liability associated with milestone payments expected to become payable in the first half of 2021 in its consolidated balance sheet at September 30, 2020.

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 a loan 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. The Company received a loan of approximately $367,000. The loan matures in April 2022, bears interest at a rate of 1.00% per annum, is payable in equal monthly payments commencing in November 2020 through maturity and may be prepaid at any time prior to maturity with no prepayment penalties. 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. Qualifying expenses include payroll costs, costs used to continue group health care benefits, mortgage interest payments, rent payments, utility payments, and interest payments on other debt obligations incurred before February 15, 2020. In September 2020, the Company submitted its forgiveness application. The Company used the entire amount of the loan for payroll and rent costs, which the Company believes are expenses that constitute qualifying expenses, and the Company requested that the entire amount of the loan, including accrued interest, be forgiven. There can be no assurance that the loan will be forgiven, in whole or in part. Under current SBA guidance, it may take up to 90 days from the date the Company's loan forgiveness application is submitted to the SBA by the Company's lender for the SBA to make a determination with respect to the Company's loan forgiveness application . The Company recorded a note payable plus accrued interest for the loan in the amount of approximately $369,000 in its consolidated balance sheet at September 30, 2020.

9. GRANT AWARD

NIH Grant Funding

The Company has received notices of awards and grant funding from the National Institutes of Health, or the NIH to support the development of Ovaprene and DARE-FRT1. The NIH 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 grant funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a division of the NIH, for clinical development efforts supporting Ovaprene. The most recent and final notice of award the Company received was for approximately $731,000 in April 2020, substantially all of which has been funded to date.

The Company recorded credits to research and development expense for costs related to the NIH award of approximately $124,000 and $302,000 for the three months ended September 30, 2020 and September 30, 2019, respectively, and $583,000 and $920,000 for the nine months ended September 30, 2020 and September 30, 2019, respectively. At September 30, 2020, the Company recorded a receivable of approximately $69,000 for expenses incurred through such date that it believes are eligible for reimbursement under the final notice of award received in April 2020.

DARE-FRT1

In August 2020, the Company received a notice of award of a grant from the NIH to support the development of DARE-FRT1. The award in the amount of $300,000 was for what is referred to as the "Phase I" segment of the project outlined in the Company's grant application, which is to occur during the period of August 2020 through July 2021. Additional potential funding of up to approximately $2.0 million for the "Phase II" segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds. There is no guarantee the Company will receive any Phase II award. The Company recorded credits to research and development expense for costs related to the NIH award of approximately $3,000 during the three months ended September 30, 2020. At September 30, 2020, the Company recorded a receivable of approximately $3,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

Bill & Melinda Gates Foundation

The Company's wholly-owned subsidiary, Microchips, has a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation, relating to the development of the pre-clinical stage contraceptive candidate, DARE-LARC1. Expenses eligible for grant funding must be incurred, tracked and reported to the Foundation. Microchips received grant funding payments of approximately $2.9 million in July 2019, $1.6 million in June 2020 and $899,000 in September 2020. At September 30, 2020, grant funding payments associated with research and development expenses for DARE-LARC1 not yet incurred totaled approximately $2.2 million and are recorded as deferred grant funding liability in the Company's consolidated balance sheet.

10. 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,	
	2020	2019
Stock options	2,783,591	1,824,975
Warrants	1,908,643	3,750,833
Total	4,692,234	5,575,808

11. SUBSEQUENT EVENTS

ATM Sales

Between October 1, 2020 and November 11, 2020, the Company sold an aggregate of 3,987,485 shares of common stock in "at-the-market" equity offerings and received aggregate net proceeds of approximately $4.1 million.

Equity Line

Between October 1, 2020 and November 11, 2020 the Company sold an aggregate of 400,000 shares of common stock to Lincoln Park under the Purchase Agreement and received aggregate net proceeds of approximately $0.4 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our interim 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, 2019 included in our Annual Report on Form 10-K for the year ended December 31, 2019, or our 2019 10-K, filed with the Securities and Exchange Commission, or SEC, on March 27, 2020. 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 2019 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 the acceleration of innovative products for women's health. We are driven by a mission to identify, acquire and develop a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, fertility, and sexual and vaginal 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.

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

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis, or BV;
- **Ovaprene**, a hormone-free, monthly vaginal 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 for the treatment of menopausal symptoms, including vasomotor symptoms, as part of a hormone replacement therapy, or HRT, 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, or VVA, in patients with hormone-receptor positive breast cancer.

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

- **DARE-LARC1**, a combination product designed to provide long-acting, reversible contraception comprising an implantable, user-controlled wireless drug delivery system and levonorgestrel;
- **ORB-204 and ORB-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 of, product research and development and advancing our portfolio of product candidates through clinical development and regulatory approval. We expect that the majority of our development expenses for the remainder of 2020 and in 2021 will support the advancement of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue. We are subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key employees as well as third-party licensors, partners 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, dependence on third parties, and product liability.

In addition, the COVID-19 pandemic continues to rapidly evolve. Infectious disease experts have cautioned that the U.S. may experience a substantial surge in cases and hospitalizations during the cooler months, which may lead the federal government and/or state governments to impose or re-impose stay-at-home orders and shutdowns of non-essential businesses in efforts to reduce spread of the disease, such as those announced by the United Kingdom, Germany, France and other European countries in October 2020. We do not yet know the full extent of the pandemic's potential effects on our business, including the anticipated aggregate costs for development of our product candidates, on our anticipated timelines for the development of our product candidates, or on the supply chain for our clinical supplies. However, these effects could have a material adverse impact on our business and financial condition. See the risk factor titled, *The novel coronavirus (COVID-19) pandemic and efforts to reduce its spread 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 June 2020, we commenced a Phase 3, multicenter, randomized, double-blind, placebo-controlled study of DARE-BV1 (clindamycin phosphate vaginal gel, 2%) for the treatment of BV, or the DARE-BVFREE (DARE-BV1-001) study. The study enrolled 307 postmenarchal women, ages 15 and above, at 32 sites in the United States. The primary efficacy endpoint of the study is clinical cure of BV at the evaluation visit to occur 21 to 30 days after enrollment in the study, or the Day 21-30 visit, with clinical cure defined as meeting three criteria (derived from the Amsel criteria): resolution of abnormal vaginal discharge associated with BV as confirmed by the investigator; a negative 10% potassium hydroxide (KOH) "whiff test"; and the presence of clue cells at less than 20% of total epithelial cells in a saline wet mount. We anticipate having topline data from this study by year-end 2020. If the DARE-BVFREE study is successful, we expect to be in a position to submit a new drug application, or NDA, to the FDA in the first half of 2021.

We anticipate that the aggregate costs of the DARE-BV1 program through NDA filing, including the DARE-BV1FREE study, planned nonclinical studies, manufacturing activities for the program through filing of the NDA, and the NDA filing, including the credit eligible for first time filers, will be between approximately $10.0 to $12.0 million.

Ovaprene

Based on the positive results of our postcoital test (PCT) clinical trial of Ovaprene, topline data from which was announced in November 2019, 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 for a pivotal clinical study of Ovaprene. We are designing that study to evaluate the safety and efficacy of Ovaprene to prevent pregnancy when used over a period of 12 months by approximately 250 women and will seek to confirm alignment with the FDA on the study's design prior to commencement. We are conducting development activities prior to commencement of the planned pivotal study of Ovaprene that we believe will continue to advance this program and enable us to report topline data for the pivotal clinical study by year-end 2022. If successful, we expect the study's data to support a premarket approval, or PMA, submission to the FDA, as well as marketing approvals of Ovaprene in Europe and other countries worldwide.

Sildenafil Cream, 3.6%

Sildenafil Cream, 3.6% is in Phase 2b clinical development for FSAD. In December 2019, we announced that, we reached alignment with the FDA on the design of our Phase 2b clinical trial, including the patient reported outcome, or PRO, instruments to be used to screen eligible patients with FSAD and to measure achievement of the primary efficacy endpoints, namely improvement in localized genital sensations of arousal and reduction in the distress that women with FSAD experience. The Phase 2b 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. In light of disruptions resulting from the COVID-19 pandemic, we are evaluating the optimal time to commence enrollment in the Phase 2b trial to support projected topline data for the Phase 2b trial by year-end 2021.

DARE-HRT1

In July 2020, our wholly-owned Australian subsidiary commenced a Phase 1 open-label, three-arm, parallel group clinical study of DARE-HRT1 in Australia to evaluate the pharmacokinetics, or PK, and safety of DARE-HRT1 in approximately 30 healthy, post-menopausal women, at specialty women's health sites in Australia. The primary objective of the study is to describe the PK parameters of two different dose combinations (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) over 28 days. Secondary endpoints of the study include assessing the safety and tolerability of DARE-HRT1 and comparing the exposure of estradiol, estrone, and progesterone of DARE-HRT1 over 28 days against a daily combination of oral estrogen (Estrofem®) and oral progesterone (Prometrium®). If the study's rate of enrollment occurs as we currently expect, then we anticipate having topline data from this study in the first half of 2021. We anticipate that the aggregate costs of the DARE-HRT1 Phase 1 clinical study will be approximately $2.5 million. Currently, Australia's research and development tax incentive, or R&DTI, gives 43.5% of every dollar spent by eligible companies on eligible R&D activities back to those companies in a cash payment. Daré's subsidiary intends to apply for the maximum refundable cash credit then available under the Australian R&DTI program for eligible study costs incurred.

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

Recent Events

Grant Funding for DARE-FRT1 Program

In August 2020, we received a Notice of Award of a grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). The grant funding will support the development of DARE-FRT1. The award in the amount of $0.3 million was for what is referred to as the “Phase I” segment of the project outlined in our grant application, which is to occur during the period of August 2020 through July 2021. Additional potential funding of up to approximately $2.0 million for the “Phase II” segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds. There is no guarantee we will receive any Phase II award. To receive payment under the Phase I award, we must first incur expenses eligible for reimbursement and submit a detailed accounting of such expenses to the NICHD. During the nine months ended September 30, 2020 we did not submit any requests for payment under the award.

COVID-19 Update

We closely monitor the COVID-19 pandemic and actions taken in the United States and other countries to contain and treat the disease and aid economic recovery, and we continue to assess the potential impact on our employees, operations, including our clinical trials, business strategy and financial condition and performance. In response to the spread of COVID-19, in March 2020, we implemented work-from-home and restricted travel policies. In May 2020, we modified our work-from-home policy such that some of our personnel returned to working in our facilities for a portion or all of their working time. We expect to continue to modify our work-from-home and restricted travel policies as the pandemic and state and local stay-at-home orders evolve. While we have systems and technologies in place to enable our employees to work from home, and we do not believe employee productivity has been materially adversely affected to date, we may experience material adverse impacts to productivity and challenges to our ability to effectively manage and operate our business in future periods. In addition, many of our consultants, partners and vendors on which we rely heavily are subject to similar work and travel restrictions that may adversely impact their ability to perform contracted services in a timely manner or at all. Infectious disease experts have cautioned that the U.S. may experience a substantial surge in cases and hospitalizations during the cooler months, which may lead the federal government and/or state governments to impose or re-impose stay-at-home orders and shutdowns of non-essential businesses in efforts to reduce spread of the disease, such as those announced by the United Kingdom, Germany, France, and other European countries in October 2020. The effect of the pandemic and its associated restrictions may increase the anticipated aggregate costs for the development of our product candidates and may adversely impact our anticipated timelines for the development of our product candidates by, among other things, causing disruptions in the supply chain for our clinical supplies, delays in commencement of planned clinical trials, as well as in the timing and pace of subject enrollment in our ongoing clinical trials and lower than anticipated subject enrollment and completion rates, delays in submission of any applications for marketing approval of our product candidates, delays in the review and approval of our regulatory submissions by the FDA and other agencies with respect to our product candidates, and other unforeseen disruptions. The economic impact of the pandemic and the uncertainty and volatility in the capital markets it has caused, and may continue to cause, may negatively impact investor sentiment and the availability and cost of capital, and may adversely impact our ability to raise capital when needed or on terms favorable to us and our stockholders to fund our development programs and our operations. The effect of the 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. Given the high level of uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, workplace environments and capital markets, we are unable to assess the full extent of the effects of the pandemic on our business, clinical trial activities, ability to access capital or on healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our business and financial condition. See the risk factor titled, *The novel coronavirus (COVID-19) and efforts to reduce its spread 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.

Financial Overview

We incurred a loss of approximately $19.0 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of approximately $63.0 million and cash and cash equivalents of approximately $5.4 million. We also had negative cash flow from operations of approximately $16.0 million during the nine months ended September 30, 2020. 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 current product candidates. The amount and timing of our capital needs will continue to depend highly on many factors, including the product development programs we choose to pursue and the pace and results of our clinical development efforts. If we do not raise capital as and when needed, we will not be able to continue development of our product candidates or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations. For additional information regarding our ability to continue as a going concern, see Note 1 to our unaudited interim consolidated financial statements contained in this report and "Liquidity and Capital Resources and Financial Condition," below.

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, we may generate revenue from 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. 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 products and the eventual successful commercialization of product candidates. 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 consultants and clinical trial sites that conduct research and development 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 the acquisitions of companies, technologies and related intellectual property, and other assets; and
- 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 our clinical-stage 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 and 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.

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 Significant Judgments and Estimates

Management's discussion and analysis of financial condition and results of operations is based on our interim 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 consolidated interim financial statements, refer to Item 7 in Management's Discussion and Analysis of Financial Condition and Results of Operations, Note 1 to our financial statements contained in our 2019 10-K, and Note 2 to our unaudited interim consolidated financial statements contained in this report.

Results of Operations

Comparison of Three Months Ended September 30, 2020 and 2019 (Unaudited)

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

	Three Months Ended September 30,		Dollar
	2020	2019	Change
Operating expenses:			
General and administrative	$ 1,353,069	$ 1,318,986	$ 34,083
Research and development	6,203,753	1,966,230	4,237,523
License fees	25,000	133,333	(108,333)
Total operating expenses	7,581,822	3,418,549	4,163,273
Loss from operations	(7,581,822)	(3,418,549)	(4,163,273)
Other income	(986)	25,471	(26,457)
Net loss	$ (7,582,808)	$ (3,393,078)	$ (4,189,730)
Deemed dividend from trigger of down round provision feature	$ (6,863)	$ —	(6,863)
Net loss to common shareholders	$ (7,589,671)	$ (3,393,078)	$ (4,196,593)
Other comprehensive loss:			
Foreign currency translation adjustments	672	(15,378)	16,050
Comprehensive loss	$ (7,588,999)	$ (3,408,456)	$ (4,180,543)

Revenues

We did not recognize any revenues for either of the three months ended September 30, 2020 or 2019.

General and administrative expenses

The increase of $34,083 in general and administrative expenses for the three months ended September 30, 2020 as compared to the three months ended September 30, 2019 was primarily attributable to increases in (i) personnel costs of approximately $148,000, (ii) rent and facilities expenses of approximately $61,000, due to the addition of two leases when we acquired Microchips in November 2019, and (iii) stock-based compensation expense of approximately $26,000. These increases were partially offset by a decrease in expenses for professional services of approximately $190,000.

Research and development expenses

The increase of $4.2 million in research and development expenses for the three months ended September 30, 2020 as compared to the three months ended September 30, 2019 was primarily attributable to increases in (i) costs related to development activities of approximately $3.2 million for DARE-BV1, (ii) costs related to development activities of approximately $856,000 for Ovaprene, offset by increased grant funding recorded as a reduction to research and development expenses of approximately $178,000 related to Ovaprene, (iii) costs related to pre-clinical development activities of approximately $665,000 for DARE-LARC1, which we acquired in November 2019, (iv) personnel costs of approximately $159,000, and (v) costs related to development activities of approximately $76,000 related to DARE-FRT1. These increases were partially offset by (a) an increase in grant funding recorded as a reduction to research and development expenses of approximately $665,000 related to preclinical expenses for DARE-LARC1, (b) a decrease in costs related to development activities of approximately $212,000 for DARE-HRT1, and (c) a decrease in costs related to development activities of approximately $72,000 for Sildenafil Cream, 3.6%.

License fees

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

For the three months ended September 30, 2019 we accrued $133,333 of license expenses comprised of the $112,500 of deferred license fees due under our license agreement related to DARE-BV1 and the $20,833 of the annual license maintenance fee payable in the second quarter of 2020 under our license agreement related to DARE-HRT1.

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

Other income

The decrease of $26,457 in other income for the three months ended September 30, 2020 as compared to the three months ended September 30, 2019 was primarily due to a decrease in interest earned on cash balances in the current period.

Comparison of Nine Months Ended September 30, 2020 and 2019 (Unaudited)

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

	Nine months ended September 30, 2020	2019	Dollar Change
Operating expenses:			
General and administrative	$ 4,772,382	$ 3,903,545	$ 868,837
Research and development	14,131,007	6,172,192	7,958,815
License fees	58,333	408,333	(350,000)
Total operating expenses	18,961,722	10,484,070	8,477,652
Loss from operations	(18,961,722)	(10,484,070)	(8,477,652)
Other income	2,454	86,703	(84,249)
Net loss	$ (18,959,268)	$ (10,397,367)	$ (8,561,901)
Deemed dividend from trigger of down round provision feature	(6,863)	(789,594)	782,731
Net loss to common shareholders	$ (18,966,131)	$ (11,186,961)	$ (7,779,170)
Other comprehensive loss:			
Foreign currency translation adjustments	(10,182)	(15,674)	5,492
Comprehensive loss	$ (18,976,313)	$ (11,202,635)	$ (7,773,678)

Revenues

We did not recognize any revenues for either of the nine months ended September 30, 2020 or 2019.

General and administrative expenses

The increase of $868,837 in general and administrative expenses for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 was primarily attributable to increases in (i) personnel costs of approximately $397,000, (ii) rent and facilities expenses of approximately $175,000 due to the addition of two leases when we acquired Microchips in November 2019, (iii) expenses for professional services of approximately $118,000, (iv) stock-based compensation expense of approximately $110,000, and (v) insurance expense of approximately $42,000.

Research and development expenses

The increase of $8.0 million in research and development expenses for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 was primarily attributable to increases in (i) costs related to development activities of approximately $5.6 million for DARE-BV1, (ii) costs related to development activities of approximately $2.7 million for Ovaprene, inclusive of decreased grant funding recorded as a reduction to research and development expenses of approximately $336,000 related to Ovaprene, (iii) costs related to pre-clinical development activities of approximately $2.3 million for DARE-LARC1, which we acquired in November 2019, (iv) personnel costs of approximately $407,000, and (v) stock-based compensation expense of approximately $88,000. Those increases were partially offset by (a) an increase in grant funding recorded as a reduction to research and development expenses of approximately $2.4 million related to preclinical expenses for DARE-LARC1, (b) a decrease in costs related to development activities of approximately $393,000 for Sildenafil Cream, 3.6%, (c) a decrease in costs related to development activities of approximately $486,000 for DARE-HRT1, and (d) a decrease in costs related to pre-clinical development activities of approximately $44,000.

License fees

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 the nine months ended September 30, 2019 the $408,333 of license expenses comprised of the $337,500 of deferred license fees due under our license agreement related to DARE-BV1, the $50,000 annual license fee paid in the second quarter of 2019 under our license agreement related to DARE-HRT1, and the accrual of $20,833 of the $50,000 annual license maintenance fee due under our agreement related to DARE-HRT1 in the second quarter of 2020.

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

Other income

The decrease of $84,249 in other income for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 was primarily due to a decrease in interest earned on cash balances in the current period.

Liquidity and Capital Resources and Financial Condition

Plan of Operations and Future Funding Requirements

We prepared the accompanying 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. In addition, 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 our existing product candidates and seek to acquire, license or develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying 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, 2020, our accumulated deficit was approximately $63.0 million, our cash and cash equivalents were approximately $5.4 million, and our working capital deficit was approximately $1.0 million. We incurred a loss from operations of approximately $19.0 million, and had negative cash flow from operations of approximately $16.0 million during the nine months ended September 30, 2020.

We may raise additional capital to fund our operations through the sale and issuance of additional shares of our common stock from time to time under our equity line and in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended) under our common stock sales agreement, or our ATM sales agreement. While we control the initiation of sales of our common stock under both our equity line and ATM sales agreement, our ability to sell stock is subject to limitations and restrictions on the timing and amount of such sales under both our equity line and the ATM sales agreement, as well as under applicable securities laws and Nasdaq Stock Market rules. See the discussion of our equity line and ATM sales agreement in Note 6 to our unaudited interim consolidated financial statements contained in this report. See also the risk factor titled, *Our ability to raise capital may be limited by laws and regulations* in Part I, Item 1A. Risk Factors of our 2019 10-K, and the risk factor titled, *The sale of our common stock through our ATM sales agreement or our Purchase Agreement 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,* in Part II, Item 1A. Risk Factors of this report.

In April 2020, due to the economic uncertainty resulting from the impact of the COVID-19 pandemic on our operations and to support our ongoing operations and retain all employees, we applied for a loan 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. We received a loan of approximately $367,000. The loan matures in April 2022, bears interest at a rate of 1.00% per annum, is payable in equal monthly payments commencing in November 2020 through maturity and may be prepaid at any time prior to maturity with no prepayment penalties. Under the terms of the PPP, certain amounts of the loan, including accrued interest, may be forgiven. In September 2020, we submitted our forgiveness application and we requested that the entire amount of the loan, including accrued interest, be forgiven. There can be no assurance that the loan will be forgiven, in whole or in part. Under current SBA guidance, it may take up to 90 days from the date our loan forgiveness application is submitted to the SBA by our lender for the SBA to make a determination with respect to our loan forgiveness application. For further information regarding this loan, see the discussion in Note 8 to our unaudited interim consolidated financial statements contained in this report.

The cash used to fund our operations comes from a variety of sources. During the nine months ended September 30, 2020, we received (1) approximately $10.4 million in net proceeds from sales of shares of our common stock under our ATM sales agreement; (2) approximately $4.1 million in net proceeds from sales of shares of our common stock under our equity line; (3) approximately $2.5 million under an existing grant from the Bill & Melinda Gates Foundation that funded a portion of research and development expenses for DARE-LARC1; (4) approximately $1.8 million upon the exercise of warrants to purchase 1.8 million shares of our common stock; (5) a $1.0 million upfront non-refundable license fee payment under our license agreement with Bayer HealthCare, LLC, (6) approximately $650,000 under an existing grant from the National Institutes of Health that funded a portion of the Ovaprene PCT clinical study costs; and (7) approximately $367,000 in loan proceeds under the PPP. Subsequent to September 30, 2020 and through November 11, 2020, we received (a) approximately $4.1 million in net proceeds from sales of shares of our common stock under our ATM sales agreement; and (b) approximately $398,000 in net proceeds from sales of shares of our common stock under our equity line.

Our primary uses of capital are, and we expect will continue to be, staff-related expenses, the cost of clinical trials and regulatory activities related to our product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments due under license or merger agreements upon the successful achievement of milestones of our product candidates, legal expenses, other regulatory expenses and general overhead costs.

We continue to expect our expenses, and in particular our research and development expenses, for the year ending 2020 to be significantly greater than they were for 2019 as we continue the development of our product candidates, with a focus on DARE-BV1, Sildenafil Cream, 3.6%, Ovaprene, and DARE-HRT1, as discussed above, and as we incur license expenses associated therewith and as milestones associated therewith are achieved. We currently anticipate that, during the first half of 2021, $1.0 million in milestone payments will become payable under the merger agreement pursuant to which we acquired Microchips in November 2019.

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, and 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 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 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 will 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 interim consolidated financial statements.

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

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders, and the uncertainty and volatility in the capital markets caused by the COVID-19 pandemic may negatively impact the availability and cost of capital and investor sentiment. In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders. 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,	
	2020	**2019**
Net cash used in operating activities	(16,041,176)	(9,506,797)
Net cash provided by investing activities	(15,246)	—
Net cash provided by financing activities	16,675,911	5,151,702
Effect of exchange rate changes on cash and cash equivalents	(10,182)	(15,674)
Net increase (decrease) in cash and cash equivalents	$ 609,307	$ (4,370,769)

Net cash used in operating activities

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 a $472,000 increase in accounts payable, a $1.0 million increase in deferred license revenue, a $342,000 decrease in other receivables, a $355,000 increase in accrued expenses, a $159,000 increase in deferred grant funding, a $118,000 decrease in other non-current assets, and a $18,700 increase in prepaid expenses.

Cash used in operating activities for the nine months ended September 30, 2019 included the net loss of $10.4 million, decreased by non-cash stock-based compensation expense of $344,712. A $367,409 increase in prepaid expenses and a $107,463 decrease in accounts payable reduced operating cash in this period. A $905,236 increase in accrued expenses and a $138,719 increase in other non-current assets and deferred charges provided operating cash in this period.

Net cash provided by financing activities

Cash provided by financing activities for the nine months ended September 30, 2020 included approximately $10.4 million of net proceeds from the sales of an aggregate of 7,916,092 shares of our common stock in "at-the-market" offerings completed during the period, approximately $1.8 million received upon the exercise of warrants to purchase 1.8 million shares of our common stock, approximately $4.1 million of net proceeds from the sales of an aggregate of 3,882,160 shares of common stock under our equity line, and approximately $367,000 in loan proceeds under the PPP.

Cash provided by financing activities for the nine months ended September 30, 2019 consisted of proceeds from the underwritten public offering completed in April 2019.

Net cash used in investing activities

Cash used in investing activities for the nine months ended September 30, 2020 was $15,246. No cash was provided by or used in investing activities for the nine months ended September 30, 2019.

License and Royalty Agreements

We have 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 interim 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) that are 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, 2020 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 and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. There are no material pending legal proceedings, other than ordinary routine litigation incidental to our business, to which we are a party or of which any of our property is in the subject.

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 2019 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 2019 10-K other than as described below:

Risks Related to Our Business

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, 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 research and development activities and production and supply of clinical trial materials. 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 increase in personnel working 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.

The pandemic could cause delays in current timelines for our planned clinical studies. As of the date of this report, we expect to report topline data for the Phase 3 study of DARE-BV1 by year-end 2020, and we expect to commence, or continue to conduct, clinical studies such that we can report topline data for the Phase 1 study of DARE-HRT1 and the Phase 2b study of Sildenafil Cream, 3.6% in 2021, and for the pivotal study of Ovaprene in 2022. However, the pandemic may adversely impact these expectations. For example, clinical 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.

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. We currently do not have adequate capital to complete all of our planned clinical studies on our current timelines. 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 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.

Further, 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. We do not have, and do not currently plan to develop, the internal sales, marketing and distribution infrastructure necessary to independently market and sell our product candidates, if approved.

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. However, there can be no assurance that such plans will be effective in mitigating the potential adverse effects of the pandemic on our ongoing clinical trials, on the productivity of our employees or on our business, financial condition and results of operations.

The extent to which the pandemic and efforts to reduce its spread impacts 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 information that may emerge concerning the degree to which COVID-19 is contagious and virulent, the effect of actions taken in the United States and other countries to contain and treat COVID-19, and further actions implemented to contain and treat the disease and its impact, among others.

The pandemic may also have the effect of heightening many of the other risks and uncertainties described the "Risk Factors" section of our 2019 10-K.

Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our third-party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information or expose us to liability, any of which could adversely affect our business and our reputation.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including deliberate attacks, the deployment of harmful malware or ransomware, denial of service, and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and those of our third-party service providers, and could compromise the confidentiality, availability and integrity of our data, confidential information, or other intellectual property, all of which are vital to our operations and business strategy. There can be no assurance we will succeed in preventing cyber-attacks or successfully mitigate their effects.

Despite implementing security measures, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failure. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For example, losing clinical study data from future clinical studies could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. In addition, a security breach or privacy violation that leads to disclosure of personally identifiable information or protected health information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and subject us to litigation or other liability under laws and regulations that protect personal data. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure, which could disrupt our operations. If any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability, our product development programs and competitive position may be adversely affected, and the further development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

Risks Related to Clinical Development, Manufacturing and Commercialization

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, and others, including regulatory authorities, may not agree with our interpretation of study data.

From time to time, we may publicly disclose interim, preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. There can be no guarantee that a favorable futility analysis will result in a favorable final result at the completion of the clinical trial.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of study data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. For example, even if we report positive topline data for the DARE-BVFREE study, FDA may still require the conduct of additional efficacy or safety trials before it will accept a DARE-BV1 NDA for filing or approve the NDA.

Risks Related to Ownership of Our Common Stock

The sale of our common stock through our ATM sales agreement or our Purchase Agreement 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.

In January 2018, we entered into the ATM sales agreement , under which, from time to time, we may offer and sell shares of our common stock. In April 2020, we entered into the Purchase Agreement with Lincoln Park. The purchase price for the shares we may sell under our Purchase Agreement will vary based the market price of our common stock at the time we initiate a sale. Although we have the right to control whether we sell any shares, if at all, under these agreements, and we generally have the right to control the timing and amount of any such sales, we are subject to certain restrictions, including those that limit the number of shares we may sell. For example, based on our current public float, during any 12-month period, we may not sell securities under our shelf registration statement 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, which limits the amount of shares we can sell under the ATM sales agreement. In addition, with respect to the Purchase Agreement, we may not sell more than 4,941,089 shares to Lincoln Park, which we refer to as the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price per share of all sales to Lincoln Park equals or exceeds $1.0117, and we may not sell shares to Lincoln Park if it would result in Lincoln Park beneficially owning more than 9.99% of our then outstanding shares of common stock. Accordingly, we may not be able to utilize the ATM sales agreement or the Purchase Agreement to raise additional capital when, or in the amounts, we desire. However, to the extent we do sell shares of our common stock under these agreements, such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline.

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

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.
(b) None.

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
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

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 12, 2020

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

Date: November 12, 2020

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

Exhibit 31.1

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

/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 12, 2020

/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, 2020, 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 12, 2020

/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, 2020, 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 12, 2020

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