

**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 **March 31, 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)

**Commission File No. 001-36395**

**20-4139823**  
(IRS Employer  
Identification No.)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**3655 Nobel Drive, Suite 260**  
**San Diego, CA**  
(Address of Principal Executive Offices)

**(858) 926-7655**  
(Registrant's telephone number, including area code)

**92122**  
(Zip Code)

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

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

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

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  No

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  No

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

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

As of May 12, 2020, 26,646,191 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 on acceptable terms;
- A decision by Bayer HealthCare LLC to discontinue its commercial interest in Ovaprene® and/or to terminate our license agreement;
- 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;
- Inability to develop 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;
- 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;
- 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;
- 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;*
- *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 the Company's 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

	March 31, 2020  (unaudited)	December 31, 2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 5,047,325	\$ 4,780,107
Other receivables	429,722	555,210
Prepaid expenses	3,844,764	1,108,615
<b>Total current assets</b>	<b>9,321,811</b>	<b>6,443,932</b>
Property and equipment, net	51,582	63,531
Other non-current assets	840,572	935,325
<b>Total assets</b>	<b>\$ 10,213,965</b>	<b>\$ 7,442,788</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,531,497	\$ 1,083,183
Accrued expenses	1,690,626	2,098,653
Deferred grant funding	1,089,064	2,019,674
Current portion of lease liabilities	404,395	410,896
<b>Total current liabilities</b>	<b>4,715,582</b>	<b>5,612,406</b>
Deferred license revenue	1,000,000	—
Contingent consideration	1,000,000	1,000,000
Lease liabilities long-term	284,200	389,556
<b>Total liabilities</b>	<b>6,999,782</b>	<b>7,001,962</b>
Commitments and contingencies (Note 8)	—	—
<b>Stockholders' equity</b>		
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; 24,700,553 and 19,683,401 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	2,470	1,968
Accumulated other comprehensive loss	(125,569)	(102,625)
Additional paid-in capital	51,612,721	44,564,674
Accumulated deficit	(48,275,439)	(44,023,191)
<b>Total stockholders' equity</b>	<b>3,214,183</b>	<b>440,826</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 10,213,965</b>	<b>\$ 7,442,788</b>

See accompanying notes to interim consolidated financial statements.

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

	Three months ended March 31,	
	2020	2019
<b>Operating expenses</b>		
General and administrative	\$ 1,861,765	\$ 1,277,180
Research and development	2,379,804	1,693,391
License fees	12,500	112,500
<b>Total operating expenses</b>	<b>4,254,069</b>	<b>3,083,071</b>
<b>Loss from operations</b>	<b>(4,254,069)</b>	<b>(3,083,071)</b>
Other income	1,821	31,231
<b>Net loss</b>	<b>\$ (4,252,248)</b>	<b>\$ (3,051,840)</b>
Foreign currency translation adjustments	\$ (22,944)	\$ 7,621
<b>Comprehensive loss</b>	<b>\$ (4,275,192)</b>	<b>\$ (3,044,219)</b>
Loss per common share - basic and diluted	\$ (0.18)	\$ (0.27)
Weighted average number of common shares outstanding:		
Basic and diluted	23,799,396	11,422,161

See accompanying notes to interim consolidated financial statements.

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

**Three Months Ended March 31, 2020**

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balance at December 31, 2019</b>	<b>19,683,401</b>	<b>\$ 1,968</b>	<b>\$ 44,564,674</b>	<b>\$ (102,625)</b>	<b>\$ (44,023,191)</b>	<b>\$ 440,826</b>
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)
<b>Balance at March 31, 2020</b>	<b>24,700,553</b>	<b>\$ 2,470</b>	<b>\$ 51,612,721</b>	<b>\$ (125,569)</b>	<b>\$ (48,275,439)</b>	<b>\$ 3,214,183</b>

**Three Months Ended March 31, 2019**

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balance at December 31, 2018</b>	<b>11,422,161</b>	<b>\$ 1,143</b>	<b>\$ 35,791,972</b>	<b>\$ (96,728)</b>	<b>\$ (28,969,767)</b>	<b>\$ 6,726,620</b>
Stock-based compensation	—	—	97,968	—	—	97,968
Net loss	—	—	—	—	(3,051,840)	(3,051,840)
Foreign currency translation adjustments	—	—	—	7,621	—	7,621
<b>Balance at March 31, 2019</b>	<b>11,422,161</b>	<b>\$ 1,143</b>	<b>\$ 35,889,940</b>	<b>\$ (89,107)</b>	<b>\$ (32,021,607)</b>	<b>\$ 3,780,369</b>

See accompanying notes to interim consolidated financial statements.



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

	Three months ended March 31,	
	2020	2019
<b>Operating activities:</b>		
Net loss	\$ (4,252,248)	\$ (3,051,840)
<b>Non-cash adjustments reconciling net loss to operating cash flows:</b>		
Depreciation	11,949	1,150
Stock-based compensation	160,841	97,968
Non-cash operating lease cost	(55,786)	419
<b>Changes in operating assets and liabilities:</b>		
Other receivables	125,488	(135,676)
Prepaid expenses	(2,736,149)	(201,129)
Other non-current assets	38,682	55,233
Accounts payable	448,314	(134,087)
Accrued expenses	(408,027)	59,478
Deferred grant funding	(930,610)	—
Deferred license revenue	1,000,000	—
<b>Net cash used in operating activities</b>	<b>(6,597,546)</b>	<b>(3,308,484)</b>
<b>Financing activities:</b>		
Net proceeds from issuance of common stock	5,222,687	—
Proceeds from the exercise of common stock warrants	1,665,020	—
Proceeds from the exercise of stock options	1	—
<b>Net cash provided by financing activities</b>	<b>6,887,708</b>	<b>—</b>
Effect of exchange rate changes on cash and cash equivalents	(22,944)	7,621
<b>Net change in cash and cash equivalents</b>	<b>267,218</b>	<b>(3,300,863)</b>
Cash and cash equivalents, beginning of period	4,780,107	6,805,889
<b>Cash and cash equivalents, end of period</b>	<b>\$ 5,047,325</b>	<b>\$ 3,505,026</b>
<b>Supplemental disclosure of non-cash operating and financing activities:</b>		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	\$ —	\$ 231,698
		—

See accompanying notes to interim consolidated financial statements.

**Daré Bioscience, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements (Unaudited)**

**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, develop and bring to market a diverse portfolio of novel therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. The Company's business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in the Company's areas of focus, some of which have existing clinical proof-of-concept data, and to advance those candidates through clinical development and regulatory approval alone or in collaboration with strategic partners.

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 global commercialization and development strategy involves partnering with pharmaceutical companies and regional distributors with established marketing and sales capabilities in women's health, including through co-development and promotion agreements, once the Company has advanced a candidate through mid- to late-stage clinical development.

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, or BV;
- **Ovaprene®**, a hormone-free, monthly vaginal contraceptive;
- **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;

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

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

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

- A microchip-based, implantable drug delivery system and a contraceptive application of that technology utilizing levonorgestrel that is designed to provide user-controlled, long-acting, reversible contraception
- **ORB-204 and ORB-214**, 6-month and 12-month formulations of injectable etonogestrel for contraception; 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 in 2020 and 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 individuals, 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 its 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 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 March 31, 2020, the Company had an accumulated deficit of approximately \$48.3 million and cash and cash equivalents of approximately \$5.0 million. The Company also had negative cash flow from operations of approximately \$6.6 million during the three months ended March 31, 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 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 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 its spread 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 COVID-19 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, and the speed with which and degree to which normal economic and operating conditions resume. 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 timing and pace of subject enrollment in 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 COVID-19 pandemic and the uncertainty and volatility in the capital markets it 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. The Company does not yet know the full extent of potential delays or impacts on its 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 the Company's business and financial condition.

## **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 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 March 31, 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 March 31, 2020.

	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
<b>Balance at March 31, 2020</b>				
<b>Current assets:</b>				
Cash and cash equivalents	\$ 5,047,325	\$ —	\$ —	\$ 5,047,325
<b>Other non-current liabilities:</b>				
Contingent consideration	\$ —	\$ —	\$ 1,000,000	\$ 1,000,000
<b>Balance at December 31, 2019</b>				
<b>Current assets:</b>				
Cash and cash equivalents	\$ 4,780,107	\$ —	\$ —	\$ 4,780,107
<b>Other non-current liabilities:</b>				
Contingent consideration	\$ —	\$ —	\$ 1,000,000	\$ 1,000,000

### Revenue Recognition

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

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

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

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

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

The Company concluded that there was one significant performance obligation under the Bayer license agreement related to the \$1.0 million upfront non-refundable license fee payment: a distinct license to commercialize Ovaprene effective upon the receipt of the Clinical Trial and Manufacturing Activities Fee. The \$1.0 million upfront non-refundable license fee payment will be recorded as license revenue at the point in time the Company receives the Clinical Trial and Manufacturing Activities Fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license or if the agreement is terminated by Bayer. As of March 31, 2020, neither of the foregoing had occurred. The \$1.0 million upfront non-refundable license fee payment is recorded as deferred revenue in the Company's consolidated balance sheet at March 31, 2020.

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**

#### ***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 used to treat certain bacterial infections, including BV, and has been engineered to produce a dual release pattern after vaginal application, providing maximum duration of exposure to clindamycin at the site of infection. 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; 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 us 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.

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

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

*Term.* Unless earlier terminated, the license continues on a country-by-country basis until the later of the life of the licensed patents or final commercial sale of Ovaprene. In addition to customary termination rights for both parties: (A) the Company may terminate the agreement with or without cause in whole or on a country-by-country basis upon 60 days prior written notice; and (B) ADVA-Tec may terminate the agreement if (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.

### **Bayer HealthCare License Agreement**

On January 10, 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. 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, or the Clinical Trial and Manufacturing Activities Fee, 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. Such license would be exclusive with regard to commercialization and co-exclusive with the Company with regard to development.

*Milestone & Royalty Payments.* The Company would also 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 will be responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer will support 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 Clinical Trial and Manufacturing Activities Fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

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

### **SST License and Collaboration Agreement**

In February 2018, the Company entered into a license and collaboration agreement with Strategic Science & Technologies-D, LLC and Strategic Science & Technologies, LLC, referred to collectively as SST, under which the Company received an exclusive, royalty-bearing, sublicensable license to develop and commercialize, in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, the Licensed Product, which is defined as SST's topical formulation of Sildenafil Cream, 3.6% as it existed as of the effective date of the agreement, or any other topically applied pharmaceutical product containing



sildenafil or a salt thereof as a pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen.

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

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

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

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

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

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

### **Catalent JNP License Agreement**

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

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

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

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

*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.

### **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 DARE-VVA1, a proprietary vaginal formulation of tamoxifen, 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.

#### ***Microchips Acquisition***

In November 2019, the Company completed its acquisition of Microchips Biotech, Inc., or Microchips. On the closing date of the merger, Microchips became a wholly owned subsidiary of the Company. The Company acquired Microchips to secure the rights to develop user-controlled, long-acting reversible contraception that utilizes levonorgestrel. 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.

*Milestone and Royalty Payments.* 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 the implantable contraceptive product in development by Microchips. The Company expects approximately \$1.0 million of the contingent consideration payments to become payable through 2021.

#### ***Orbis Development and Option Agreement***

In March 2018, the Company entered into an exclusive development and option agreement with Orbis Biosciences, or Orbis, 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 Orbis \$300,000 to conduct the first stage of development work, Stage 1, as follows: \$150,000 upon signing the agreement, \$75,000 at the 50% completion point, not later than 6 months following the date the agreement was signed (which the Company paid in September 2018), and \$75,000 upon delivery by Orbis 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 Orbis successfully completing Stage 1 of the development program and achieving the predetermined target milestones for Stage 1, the Company will have 90 days to instruct Orbis whether to commence the second stage of development work, Stage 2. Should the Company execute its option to proceed to Stage 2, it will have to provide additional funding to Orbis 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 Orbis 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.

## **4. ACQUISITIONS**

#### ***Microchips Acquisition***

In November 2019, the Company acquired Microchips Biotech, Inc., or Microchips, via a merger transaction in which a wholly owned subsidiary 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, microchip-based, 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.

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 (1) contingent consideration based upon the achievement of specified funding, product development and regulatory milestones, and upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property the Company acquired in the merger, (2) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, and (3) a percentage of sublicense revenue related to such products. The Company recorded \$1.0 million in contingent consideration associated with milestone payments expected to become payable through 2021.

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 March 31, 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 three months ended March 31, 2020 or March 31, 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 three months ended March 31, 2020. The exercise price of all options granted during the three months ended March 31, 2020 was equal to the market value of the Company's common stock on the date of grant. As of March 31, 2020, unamortized stock-based compensation expense of \$1,686,903 will be amortized over a weighted average period of 2.9 years. At March 31, 2020, 704,481 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	707,000	1.06
Exercised	(10,149)	0.01
Canceled/forfeited	—	—
Expired	—	—
Outstanding at March 31, 2020	2,586,626	\$ 1.17
Exercisable at March 31, 2020	568,118	\$ 1.86

### 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 March 31,	
	2020	2019
Research and development	\$ 46,380	\$ 24,703
General and administrative	114,461	73,265
Total	\$ 160,841	\$ 97,968

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 months ended March 31, 2020 are as follows:

	Three Months Ended March 31, 2020
Expected life in years	10.0
Risk-free interest rate	0.86%
Expected volatility	121%
Forfeiture rate	0.0%
Dividend yield	0.0%
Weighted-average fair value of options granted	\$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 March 31, 2020, the Company sold 3,308,003 shares under the common stock sales agreement for gross proceeds of approximately \$5.4 million and incurred offering expenses of approximately \$220,000. The Company did not sell any shares under this agreement during the three months ended March 31, 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.

### **Common Stock Warrants**

The warrants issued in the February 2018 underwritten offering 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 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, in accordance with the price-based anti-dilution provision discussed above, as a result of the sale of shares in the April 2019 underwritten offering, the exercise price of these warrants was automatically reduced to \$0.98 per share and \$0.8 million was recorded to additional paid-in capital as a result of the triggering of the anti-dilution provision.

During the three months ended March 31, 2020, 1,699,000 warrants were exercised for gross proceeds of approximately \$1.7 million. No warrants were exercised during the three months ended March 31, 2019. As of March 31, 2020, the Company had the following warrants outstanding:

<b>Shares Underlying Outstanding Warrants</b>		<b>Exercise Price</b>	<b>Expiration Date</b>
2,906	\$	120.40	December 1, 2021
3,737	\$	120.40	December 6, 2021
6,500	\$	10.00	April 4, 2026
2,021,500	\$	0.98	February 15, 2023
2,034,643			

## 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 Company 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 March 31, 2020, the Company reported operating lease right of use assets of approximately \$432,000 in other non-current assets, and \$404,000 and \$284,000, 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 March 31, 2020 and March 31, 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 was approximately \$128,000 and \$27,000 for three months ended March 31, 2020 and March 31, 2019, respectively, and these amounts are included in operating activities in the consolidated statements of cash flows. Further, at March 31, 2020, operating leases had a weighted average remaining lease term of 1.61 years.

As of March 31, 2020, future minimum payments under the Company's operating leases are approximately:

Remainder of 2020	\$	334,000
2021		363,000
2022		42,000
<b>Total future minimum lease payments</b>		<b>739,000</b>
Less: Difference between future minimum lease payments and discounted operating lease liabilities		50,000
<b>Total operating lease liabilities</b>	<b>\$</b>	<b>689,000</b>

## 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 through 2021 in its consolidated balance sheet at March 31, 2020.

## 9. GRANT AWARD

### ***Eunice Kennedy Shriver National Institute of Child Health and Human Development***

Since 2018, the Company has received grant funding for clinical development efforts supporting Ovaprene from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a division of the National Institutes of Health, or the NIH. Through year-end 2019, the Company received award payments from the NIH totaling \$1.2 million.

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.

The Company recorded credits to research and development expense for costs related to the NIH award of approximately \$293,000 and \$161,000 for the three months ended March 31, 2020 and March 31, 2019, respectively.

### ***Bill & Melinda Gates Foundation***

Microchips has a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation, relating to the development of Microchips' contraceptive program. Expenses eligible for grant funding must be incurred, tracked and reported to the Foundation. In July 2019, Microchips received approximately \$2.9 million in grant funding payments. At March 31, 2020, grant funding payments associated with research and development expenses for Microchips' contraceptive program not yet incurred totaled approximately \$1.1 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 March 31,	
	2020	2019
Stock options	2,586,626	2,190,360
Warrants	2,034,643	3,750,833
Total	4,621,269	5,941,193

## 11. SUBSEQUENT EVENTS

### ***NIH Grant Award***

In April 2020, the Company received a final notice of award for approximately \$731,000 of the total \$1.9 million in grant funding for clinical development efforts supporting Ovaprene from the NIH. At March 31, 2020, the Company recorded a receivable of approximately \$428,000 for expenses incurred through such date that are eligible for reimbursement under this final notice of award. The NIH issued this final notice of award after reviewing data from the completed postcoital test (or PCT) clinical trial and commercialization plans of Ovaprene, which satisfied specified requirements set out in the award notice.

### ***Paycheck Protection Program***

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 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, subject to specified limitations, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period that begins on the date the lender makes the first disbursement to the borrower. The Company intends to use the entire loan for qualifying expenses under the PPP and to apply for forgiveness of the entire loan, however, no assurance is provided that the Company will obtain forgiveness of the loan in whole or in part.

### ***Equity Line***

On April 22, 2020, the Company entered into a Purchase Agreement and 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, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the date that a registration statement covering the resale by Lincoln Park of shares that have been and may be issued under the Purchase Agreement is declared effective by the SEC and a final prospectus in connection therewith is filed and the other conditions in the Purchase Agreement are satisfied. The Company filed such a registration statement with the SEC on May 1, 2020 to register the resale by Lincoln Park of up to 7,500,000 shares of the Company's common stock and it was declared effective on May 12, 2020.

### ***ATM Sales***

Between April 1, 2020 and May 12, 2020, the Company sold an aggregate of 1,864,485 shares of common stock in "at-the-market" equity offerings and received aggregate net proceeds of approximately \$2.0 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 in 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, and to take those candidates through advanced stages of clinical development, and then out-license these products to companies with sales and distribution capabilities in women's health to leverage their commercial capabilities. We and our wholly owned subsidiaries operate in one business segment.

Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through mid- and late stages of clinical development or approval. Our global commercialization and development strategy involves partnering with pharmaceutical companies and regional distributors with established marketing and sales capabilities in women's health, including through co-development and promotion agreements, once we have advanced a candidate through mid- to late-stage clinical development.

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 that we believe are Phase 1-ready:

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

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

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

- A microchip-based, implantable drug delivery system and a contraceptive application of that technology utilizing levonorgestrel that is designed to provide user-controlled, long-acting, reversible contraception
- **ORB-204 and ORB-214**, 6-month and 12-month formulations of injectable etonogestrel for contraception; 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 in 2020 and 2021 will support the advancement of DARE-BV1, Oviprene 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 individuals, 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. We do not yet know the full extent of its 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," below.*

## Clinical Stage Product Candidates

### DARE-BV1

We are currently working on regulatory and start-up activities that are necessary to commence a Phase 3 multicenter, randomized, double-blind, placebo-controlled study of DARE-BV1 for the treatment of BV, or the DARE-BV1-001 study, and expect to initiate the study in the second half of 2020. We plan to enroll approximately 220 postmenarchal women, ages 12 and above, at approximately 40 sites in the United States. The primary efficacy endpoint of the study will be clinical cure 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. If the study's initiation and rate of subject enrollment occur as we currently expect, then we anticipate having topline data from this study before year-end 2020. In parallel with the DARE-BV1-001 clinical study and to support the new drug application, or NDA, for DARE-BV1, we are conducting nonclinical studies of certain excipients in DARE-BV1 and the clinical formulation of DARE-BV1, including reproductive toxicology studies. If the DARE-BV1-001 clinical study and the nonclinical studies are completed as anticipated and if their outcomes are successful, then we expect to be in a position to file an NDA with the FDA in early 2021.

We anticipate that the aggregate costs of the DARE-BV1 program through NDA filing, including the DARE-BV1-001 study, planned nonclinical studies, manufacturing activities for the program through filing of the NDA, and the NDA filing, will be approximately \$10.0 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 (discussed below under "Recent Events"), 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. In light of disruptions resulting from the COVID-19 pandemic and prioritization of non-clinical activities that can be efficiently advanced in the COVID-19 environment, we no longer plan to commence the study in 2020. However, we expect the development activities we are conducting, and plan to conduct, in the interim will continue to advance this program and we continue to expect to report topline data for the planned pivotal clinical study of Ovaprene 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 and are currently considering commencing in late 2020 or early 2021. Even if we commence in early 2021, we continue to expect to report topline data for the Phase 2b trial by year-end 2021.

## **DARE-HRT1**

We plan to conduct 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. The primary objectives of the study are 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, and to identify the steady state PK of each dose combination after 28 days. We currently continue to expect to report topline results of this clinical study by the end of 2020.

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 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," below.

## **Recent Events**

### **COVID-19 Update**

In response to the spread of COVID-19, in March 2020 we implemented work-from-home and restricted travel policies and, subsequently, the governors of California and Massachusetts, where we have operations, issued statewide stay-at-home orders. While we have systems and technologies in place to enable our employees to work from home, productivity may be adversely impacted and challenge our ability to effectively manage and operate our business. 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. 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 COVID-19 pandemic and state and local stay-at-home orders evolve. The effect of the COVID-19 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 the timing and pace of subject enrollment in our clinical trials and lower than anticipated subject enrollment and completion rates, 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 COVID-19 pandemic and the uncertainty and volatility in the capital markets it 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. We do not yet know the full extent of potential delays or impacts 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) 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," below.

### **Equity Line**

On April 22, 2020, we entered into a purchase agreement, or the equity line 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 Equity line agreement, we may sell to Lincoln Park up to \$15.0 million in shares of our common stock. Such sales of our common stock, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the date that a registration statement covering the resale by Lincoln Park of shares that have been and may be issued under the equity line agreement is declared effective by the Securities and Exchange Commission, or the SEC, and the other conditions in the equity line agreement are satisfied. We refer to the date on which all such conditions are satisfied, as the Commencement Date. We filed such a registration statement with the SEC on May 1, 2020 to register the resale by Lincoln Park of up to 7,500,000 shares of the Company's common stock and it was declared effective on May 12, 2020.

On the Commencement Date, we may direct Lincoln Park to purchase up to \$500,000 in shares of our common stock, or the Commencement Purchase. Thereafter, on any business day we may direct Lincoln Park to purchase up to 200,000 shares of our common stock, each, a Regular Purchase; provided that the share amount under a Regular Purchase may be increased to up to 250,000 shares or up to 300,000 shares if the closing sale price of our common stock is not below \$1.50 or \$3.00, respectively, on the business day on which we initiate the purchase, subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction as provided in the equity line agreement. However, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$1,000,000. The purchase price per share for the Commencement Purchase and each Regular Purchase will be the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the purchase and (ii) the average of the three lowest closing sale prices of our common stock during the 10-business day period immediately preceding the business day on which we initiate the purchase. In addition to Regular Purchases, we 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 equity line agreement, at a purchase price per share calculated as specified in the equity line agreement, but in no case lower than the minimum price per share we stipulate in our notice to Lincoln Park initiating these purchases.

Sales of shares of our common stock to Lincoln Park under the equity line agreement will depend 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. The net proceeds we receive under the equity line agreement will depend on the frequency and prices at which we sell shares to Lincoln Park. We expect that any proceeds we receive from such sales will be used for working capital and general corporate purposes.

In addition, under applicable Nasdaq rules, we may not issue or sell to Lincoln Park under the equity line agreement more than 4,941,089 shares of our common stock, which we refer to as the Exchange Cap, unless (i) we obtain stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the equity line agreement equals or exceeds \$1.0117 (which represents the closing sale price per share of our common stock on the day before we entered into the equity line agreement, plus an incremental amount), such that issuances and sales of common stock to Lincoln Park under the equity line agreement would not be subject to the Exchange Cap under applicable Nasdaq rules. We may also not sell shares to Lincoln Park under the equity line agreement if it would result in Lincoln Park beneficially owning more than 9.99% of our then outstanding shares of common stock.

In connection with entering into the equity line agreement, on April 22, 2020, we issued 285,714 shares of our common stock to Lincoln Park in consideration for its commitment to purchase shares under the equity line agreement.

## ***License Agreement with Bayer HealthCare***

On January 10, 2020 we entered into a license agreement with Bayer HealthCare LLC, or Bayer, regarding the further development and commercialization of Ovaprene in the U.S. We received a \$1.0 million upfront non-refundable license fee payment from Bayer. We will be responsible for the pivotal trial for Ovaprene and for its development, regulatory activities, and we have product supply obligations. Bayer will support us in development and regulatory activities by providing the equivalent of two experts to advise us in clinical, regulatory, preclinical, commercial, CMC and product supply matters. Bayer, in its sole discretion, has the right to make the license effective by paying us an additional \$20.0 million, referred to as the "Clinical Trial and Manufacturing Activities Fee." Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with us with regard to development. We will also be entitled to receive (a) milestone payments totaling up to \$310.0 million if all such milestones are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

## **Financial Overview**

We incurred a loss of approximately \$4.3 million for the three months ended March 31, 2020. As of March 31, 2020, we had (a) an accumulated deficit of approximately \$48.3 million and (b) cash and cash equivalents of approximately \$5.0 million. We also had negative cash flow from operations of approximately \$6.6 million during the three months ended March 31, 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 future funding will depend on many factors, including 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 March 31, 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 March 31,		Dollar Change
	2020	2019	
Operating expenses:			
General and administrative	\$ 1,861,765	\$ 1,277,180	\$ 584,585
Research and development	2,379,804	1,693,391	686,413
License fees	12,500	112,500	(100,000)
Total operating expenses	<u>4,254,069</u>	<u>3,083,071</u>	<u>1,170,998</u>
Loss from operations	(4,254,069)	(3,083,071)	(1,170,998)
Other income	1,821	31,231	(29,410)
Net loss	<u>\$ (4,252,248)</u>	<u>\$ (3,051,840)</u>	<u>\$ (1,200,408)</u>
Other comprehensive loss:			
Foreign currency translation adjustments	(22,944)	7,621	(30,565)
Comprehensive loss	<u>\$ (4,275,192)</u>	<u>\$ (3,044,219)</u>	<u>\$ (1,230,973)</u>

### **Revenues**

We did not recognize any revenues for either of the three months ended March 31, 2020 or 2019.

### **General and administrative expenses**

The increase of \$584,585 in general and administrative expenses for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019 was primarily attributable to (i) an increase in expenses for accounting, legal, and professional services of approximately \$272,000, (ii) an increase in personnel costs of approximately \$136,000, (iii) an increase in insurance costs of approximately \$47,000, (iv) an increase in stock-based compensation expense of approximately \$41,000, (v) an increase in information technology expense of approximately \$25,000, and (vi) an increase in rent expense of approximately \$19,000 due to the addition of two leases acquired in conjunction with the acquisition of Microchips.

### **Research and development expenses**

The increase of \$686,413 in research and development expenses for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019 was primarily attributable to (i) an increase in pre-clinical development activities of approximately \$902,000 for our microchip-based contraceptive application, which we acquired in November 2019, (ii) an increase in costs related to development activities of approximately \$893,000 for DARE-BV1, Ovaprene, DARE-HRT1 and DARE-VVA1, (iii) an increase in personnel costs of approximately \$132,000 and (iv) an increase in stock-based compensation expense of approximately \$22,000. Those increases were partially offset by (x) an increase in grant funding recorded as a reduction to research and development expenses of approximately \$132,000 related to Ovaprene and approximately \$978,000 related to preclinical expenses for our microchip-based contraceptive application, (y) a decrease in costs related to development activities of approximately \$74,000 for Sildenafil Cream, 3.6%, and DARE-FRT1 and (z) a decrease in costs related to pre-clinical development activities of approximately \$79,000.

### **License fees**

For the three months ended March 31, 2020 we accrued \$12,500 of the \$50,000 license maintenance fee payable in the second quarter of 2020 under our license agreement related to DARE-HRT1.

The license fees expense of \$112,500 for the three months ended March 31, 2019 related to the accrual of deferred license fees due under our license agreement related to DARE-BV1.

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 \$29,410 in other income for the three months ended March 31, 2020 as compared to the three months ended March 31, 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 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 March 31, 2020, our accumulated deficit was approximately \$48.3 million, our cash and cash equivalents were approximately \$5.0 million, and our working capital was approximately \$4.6 million. We incurred a loss from operations of approximately \$4.3 million, and had negative cash flow from operations of approximately \$6.6 million during the three months ended March 31, 2020.

In January 2018, we entered into a common stock sales agreement, or our ATM agreement, under which we may sell shares of our 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). Under the terms and subject to the conditions of our equity line agreement we entered into in April 2020, we may sell up to \$15.0 million in shares of our common stock to Lincoln

Park. As of the date of this report, the conditions that must be satisfied before we can begin to sell shares of our common stock under our equity line agreement have not been satisfied. See "—Recent Events—Equity Line," above. Our ability to raise capital under our ATM agreement and equity line agreement is subject to certain limitations. See the risk factor titled, *The sale of our common stock through our ATM sales agreement or our equity line 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," below.

The cash used to fund our operations comes from a variety of sources. During the three months ended March 31, 2020, we received (1) a \$1.0 million upfront non-refundable license fee payment under our license agreement with Bayer HealthCare, LLC, (2) approximately \$5.2 million in net proceeds from the sales of an aggregate of 3,308,003 shares of our common stock under our ATM agreement; and (3) approximately \$1.7 million upon the exercise of warrants to purchase 1.7 million shares of our common stock. Subsequent to March 31, 2020 and through May 12, 2020, we received (1) approximately \$2.0 million in net proceeds from the sales of an aggregate of 1,864,485 shares of our common stock under our ATM agreement; (2) approximately \$428,000 under an existing grant from the National Institutes of Health that funded a portion of the Ovaprene PCT clinical study costs; and (3) received a loan of approximately \$367,000 under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act administered by the U.S. Small Business Administration. For further discussion of the Paycheck Protection Program loan, see Note 11 to our unaudited interim consolidated financial statements contained in this report.

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 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 to increase significantly in 2020 as compared to 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. We also expect that delaying commencement of our planned clinical study of Ovaprene in light of disruptions resulting from the COVID-19 pandemic will result in significantly less research and development expenses in 2020 than previously anticipated.

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 agreement and our equity line agreement, if and when the conditions required to be satisfied to beginning selling thereunder are satisfied, 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 financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover our operating expenses, including the development of our product candidates and any 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:

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	(6,597,546)	(3,308,484)
Net cash provided by financing activities	6,887,708	—
Effect of exchange rate changes on cash and cash equivalents	(22,944)	7,621
Net increase (decrease) in cash and cash equivalents	<u>\$ 267,218</u>	<u>\$ (3,300,863)</u>

### **Net cash used in operating activities**

Cash used in operating activities for the three months ended March 31, 2020 included the net loss of \$4.3 million, decreased by non-cash stock-based compensation expense of approximately \$161,000. Components providing operating cash were a \$448,000 increase in accounts payable, an increase of \$1.0 million in deferred license revenue and a decrease in other receivables of \$125,000. Components reducing operating cash were a \$2.7 million increase in prepaid expenses, a \$408,000 decrease in accrued expenses and a \$931,000 decrease in deferred grant funding.

Cash used in operating activities for the three months ended March 31, 2019 included the net loss of \$3.1 million, decreased by non-cash stock-based compensation expense of \$98,000. Major components reducing operating cash in this period were a \$201,000 increase in prepaid expenses, a \$136,000 increase in other receivables, and a \$134,000 decrease of accounts payable. Components providing operating cash in this period were a \$59,000 increase of accrued expenses and a \$55,000 increase in other non-current assets and deferred charges.

### **Net cash provided by financing activities**

Cash provided by financing activities for the three months ended March 31, 2020 consisted of approximately \$5.2 million of net proceeds from the sales of an aggregate of 3,308,003 shares of our common stock in "at-the-market" offerings completed during the quarter and approximately \$1.7 million upon the exercise of warrants to purchase 1.7 million shares of our common stock.

No cash was provided by financing activities for the three months ended March 31, 2019.

### **Net cash used in investing activities**

No cash was provided by or used in investing activities for the three months ended March 31, 2020 and March 31, 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 three months ended March 31, 2020, 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 March 31, 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:

***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.***

The COVID-19 pandemic and efforts to reduce its spread 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 COVID-19 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 COVID-19 pandemic could cause delays in current timelines for our planned clinical studies. As of the date of this report, we expect to commence and conduct our planned clinical studies such that we can report topline data for the Phase 3 study of DARE-BV1 and the Phase 1 study of DARE-HRT1 in 2020, the Phase 2b study of Sildenafil Cream, 3.6% in 2021, and the pivotal study of Ovaprene in 2022. However, the COVID-19 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 COVID-19 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 COVID-19 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.

We have not developed a specific and comprehensive contingency plan designed to address the challenges and risks presented by the COVID-19 pandemic and, even if and when we do develop such a plan, there can be no assurance that such plan will be effective in mitigating the potential adverse effects on our business, financial condition and results of operations.

The extent to which the COVID-19 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 COVID-19 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.

***The sale of our common stock through our ATM sales agreement or our equity line 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 a common stock sales agreement with H.C. Wainwright & Co., LLC, in connection with an "at the market" offering, under which, from time to time, we may offer and sell shares of our common stock. We refer to this agreement as our "ATM agreement." In April 2020, we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, pursuant to which Lincoln Park is obligated to purchase up to \$15.0 million in shares of our common stock, at our sole discretion, subject to the terms and conditions set forth in the agreement, including that a registration statement covering the resale by Lincoln Park of shares that have been and may be issued under the purchase agreement is declared effective by the SEC. We refer to this agreement as our "equity line agreement." The purchase price for the shares we may sell under our equity line 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 our ATM agreement. In addition, with respect to our equity line agreement, we may not sell shares to Lincoln Park in excess of the Exchange Cap (unless we obtain stockholder approval or the average price per share of all sales to Lincoln Park equals or exceeds \$1.0117) or if selling such shares 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 our ATM agreement or our equity line 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			Exhibit No.	Filed Herewith
		Form	File No.	Filing Date		
10.13(b)*	<a href="#">Amendment No. 1 to Employment Agreement between Daré Bioscience, Inc. and Sabrina Martucci Johnson dated as of March 9, 2020</a>					X
10.14(b)*	<a href="#">Amendment No. 1 to Employment Agreement between Daré Bioscience, Inc. and Lisa Walters-Hoffert dated as of March 9, 2020</a>					X
10.16+	<a href="#">License Agreement dated as of January 10, 2020 between Bayer HealthCare LLC and Daré Bioscience, Inc.</a>	10-K	001-36395	3/27/2020	10.16+	
31.1	<a href="#">Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</a>					X
31.2	<a href="#">Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</a>					X
32.1	<a href="#">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</a>					#
32.2	<a href="#">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</a>					#
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
*	Management contract or compensatory plan or arrangement					

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

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



## Signatures

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

Daré Bioscience, Inc.

Date: May 14, 2020

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

Date: May 14, 2020

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

**AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT**

This Amendment No. 1 to Employment Agreement (this "**Amendment No. 1**") is entered into as of March 9, 2020, between Daré Bioscience, Inc. (the "**Company**"), and the undersigned individual who is an executive of the Company ("**Executive**").

WHEREAS, the Company and Executive are parties to that certain employment agreement made as of August 15, 2017 (the "**Original Agreement**").

WHEREAS, the Company and Executive desire to amend the Original Agreement as stated herein and effective as of the date first set forth above (the "**Effective Date**").

NOW, THEREFORE, in consideration of the agreements herein contained and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto hereby agree as follows:

1. Amendments to the Original Agreement. As of the Effective Date:

- a. The second sentence of Section 4(d) of the Original Agreement is hereby amended and restated in its entirety to read as follows:

For purposes of this Agreement, "Cause" means (i) Executive's act(s) of gross negligence, willful misconduct or material dishonesty in the course of Executive's employment hereunder, provided that the Board of Directors of the Company (the "Board") first provides Executive with written notice of such conduct and thirty (30) days to cure such conduct, if curable (with the determination as to whether such conduct is curable to be made by the Board in its sole discretion); (ii) misappropriation (or attempted misappropriation) by Executive of any assets of the Company or any of its affiliates; (iii) the commission or attempted commission of any act of fraud or embezzlement by Executive; (iv) willful violation of any law or regulation which adversely and materially affects the Executive's ability to discharge the Executive's duties or has a direct, substantial and adverse effect on the Company; (v) Executive's material breach of this Agreement provided that the Company first provides Executive with written notice of such conduct and thirty (30) days to cure such conduct, if curable (with the determination as to whether such conduct is curable to be made by the Board in its sole discretion); (vi) any other intentional misconduct by Executive adversely affecting the business or affairs of the Company or any of its affiliates; or (v) any material failure by Executive to comply with the Company's written policies or rules, as they may be in effect from time to time during her employment with the Company, including, without limitation, the Company's corporate code of conduct and ethics and whistleblower policy.

- b. The second sentence of Section 4(g) of the Original Agreement is hereby amended and restated in its entirety to read as follows:

For purposes of this Agreement, "Good Reason" means the existence of any one or more of the following conditions without the Executive's consent, provided Executive submits written notice to the Company within 45 days of when such condition(s) first arose specifying the condition(s): (i) a material change in the Executive's title or reporting relationships (ii) a change in the Executive's position with the Company which materially reduces the Executive's authority, duties or responsibilities, or the assignment to the Executive of duties materially inconsistent with the Executive's position with the Company; (iii) a material reduction in the Executive's then current Base Salary; (iv) a relocation of Executive's place of employment by more than 35 miles from the geographic location at which such employee primarily provided services to the Company immediately before such relocation; and (v) a material breach by the Company of this Agreement

2. Miscellaneous. Except as specifically provided in this Amendment No. 1, no other amendments, revisions or changes are made to the Original Agreement. All other terms and conditions of the Original Agreement remain in full force and effect. This Amendment No. 1 may be attached to and shall form a part of the Original Agreement. This Amendment No. 1 may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Delivery of an executed counterpart of a signature page to this Amendment by facsimile or in electronic format (e.g., "pdf") or by other electronic means shall be effective as delivery of a manually executed counterpart of this Amendment No. 1. This Amendment No. 1 will be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, personal representatives, successors and permitted assigns.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 1 as of the date first written above.

**COMPANY**

Daré Bioscience, Inc.

By: /s/ WILLIAM H. RASTETTER

Name: William H. Rastetter, Ph.D.

Title: Chair of the Compensation Committee of the Board of Directors

**EXECUTIVE**

/s/ SABRINA MARTUCCI JOHNSON

Sabrina Martucci Johnson

**AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT**

This Amendment No. 1 to Employment Agreement (this "**Amendment No. 1**") is entered into as of March 9, 2020, between Daré Bioscience, Inc. (the "**Company**"), and the undersigned individual who is an executive of the Company ("**Executive**").

WHEREAS, the Company and Executive are parties to that certain employment agreement made as of August 15, 2017 (the "**Original Agreement**").

WHEREAS, the Company and Executive desire to amend the Original Agreement as stated herein and effective as of the date first set forth above (the "**Effective Date**").

NOW, THEREFORE, in consideration of the agreements herein contained and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto hereby agree as follows:

1. Amendments to the Original Agreement. As of the Effective Date:

- a. The second sentence of Section 4(d) of the Original Agreement is hereby amended and restated in its entirety to read as follows:

For purposes of this Agreement, "Cause" means (i) Executive's act(s) of gross negligence, willful misconduct or material dishonesty in the course of Executive's employment hereunder, provided that the Board of Directors of the Company (the "Board") first provides Executive with written notice of such conduct and thirty (30) days to cure such conduct, if curable (with the determination as to whether such conduct is curable to be made by the Board in its sole discretion); (ii) misappropriation (or attempted misappropriation) by Executive of any assets of the Company or any of its affiliates; (iii) the commission or attempted commission of any act of fraud or embezzlement by Executive; (iv) willful violation of any law or regulation which adversely and materially affects the Executive's ability to discharge the Executive's duties or has a direct, substantial and adverse effect on the Company; (v) Executive's material breach of this Agreement provided that the Company first provides Executive with written notice of such conduct and thirty (30) days to cure such conduct, if curable (with the determination as to whether such conduct is curable to be made by the Board in its sole discretion); (vi) any other intentional misconduct by Executive adversely affecting the business or affairs of the Company or any of its affiliates; or (v) any material failure by Executive to comply with the Company's written policies or rules, as they may be in effect from time to time during her employment with the Company, including, without limitation, the Company's corporate code of conduct and ethics and whistleblower policy.

- b. The second sentence of Section 4(g) of the Original Agreement is hereby amended and restated in its entirety to read as follows:

For purposes of this Agreement, "Good Reason" means the existence of any one or more of the following conditions without the Executive's consent, provided Executive submits written notice to the Company within 45 days of when such condition(s) first arose specifying the condition(s): (i) a material change in the Executive's title or reporting relationships (ii) a change in the Executive's position with the Company which materially reduces the Executive's authority, duties or responsibilities, or the assignment to the Executive of duties materially inconsistent with the Executive's position with the Company; (iii) a material reduction in the Executive's then current Base Salary; (iv) a relocation of Executive's place of employment by more than 35 miles from the geographic location at which such employee primarily provided services to the Company immediately before such relocation; and (v) a material breach by the Company of this Agreement

2. Miscellaneous. Except as specifically provided in this Amendment No. 1, no other amendments, revisions or changes are made to the Original Agreement. All other terms and conditions of the Original Agreement remain in full force and effect. This Amendment No. 1 may be attached to and shall form a part of the Original Agreement. This Amendment No. 1 may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Delivery of an executed counterpart of a signature page to this Amendment by facsimile or in electronic format (e.g., "pdf") or by other electronic means shall be effective as delivery of a manually executed counterpart of this Amendment No. 1. This Amendment No. 1 will be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, personal representatives, successors and permitted assigns.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 1 as of the date first written above.

**COMPANY**

Daré Bioscience, Inc.

By: /s/ WILLIAM H. RASTETTER

Name: William H. Rastetter, Ph.D.

Title: Chair of the Compensation Committee of the Board of Directors

**EXECUTIVE**

/s/ LISA WALTERS-HOFFERT

Lisa Walters-Hoffert

## 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: May 14, 2020

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

## 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: May 14, 2020

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

**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 March 31, 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: May 14, 2020

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



**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 March 31, 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: May 14, 2020

/s/ Lisa Walters-Hoffert

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Lisa Walters-Hoffert

Chief Financial Officer

(principal financial officer)