

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

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended **June 30, 2019**  
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**

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

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

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

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

**92122**  
(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<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 checked="" 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 August 13, 2019, 16,683,411 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;*
- *Inability to successfully attract partners and enter into collaborations on acceptable terms;*
- *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;*
- *A change in the FDA’s primary oversight responsibility;*
- *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 clinical trials and to manufacture product candidates;*
- *Dependence on third parties to supply clinical supplies and raw materials, drugs and other materials required to produce a finished product and to produce the quantities needed;*
- *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;*
- *Lack of precedent to help assess whether health insurance plans will cover our product candidates;*
- *The reimbursement environment relating to our product candidates at the time we obtain regulatory approval, if ever;*
- *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**

	June 30, 2019	December 31, 2018
	(unaudited)	
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 5,630,569	\$ 6,805,889
Other receivables	493,019	31,037
Prepaid expenses	437,958	403,097
<b>Total current assets</b>	<b>6,561,546</b>	<b>7,240,023</b>
Property and equipment, net	7,081	9,396
Other non-current assets	692,305	577,968
<b>Total assets</b>	<b>\$ 7,260,932</b>	<b>\$ 7,827,387</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 632,118	\$ 459,705
Accrued expenses	1,341,811	631,351
<b>Total current liabilities</b>	<b>1,973,929</b>	<b>1,091,056</b>
Other liabilities	203,948	9,711
<b>Total liabilities</b>	<b>2,177,877</b>	<b>1,100,767</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; 16,683,411 and 11,422,161 shares issued and outstanding, respectively	1,668	1,143
Accumulated other comprehensive loss	(97,024)	(96,728)
Additional paid-in capital	41,942,062	35,791,972
Accumulated deficit	(36,763,651)	(28,969,767)
<b>Total stockholders' equity</b>	<b>5,083,055</b>	<b>6,726,620</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 7,260,932</b>	<b>\$ 7,827,387</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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
<b>Operating expenses</b>				
General and administrative	\$ 1,307,379	\$ 1,157,174	\$ 2,584,559	\$ 2,460,363
Research and development expenses	2,512,572	2,217,622	4,205,963	3,304,275
License expenses	162,500	250,000	275,000	350,000
Impairment of goodwill	—	—	—	5,187,519
<b>Total operating expenses</b>	<b>3,982,451</b>	<b>3,624,796</b>	<b>7,065,522</b>	<b>11,302,157</b>
<b>Loss from operations</b>	<b>(3,982,451)</b>	<b>(3,624,796)</b>	<b>(7,065,522)</b>	<b>(11,302,157)</b>
Other income	30,001	42,626	61,232	54,370
<b>Net loss</b>	<b>\$ (3,952,450)</b>	<b>\$ (3,582,170)</b>	<b>\$ (7,004,290)</b>	<b>\$ (11,247,787)</b>
Deemed dividend from trigger of down round provision feature	(789,594)	—	(789,594)	—
<b>Net loss to common shareholders</b>	<b>\$ (4,742,044)</b>	<b>\$ (3,582,170)</b>	<b>\$ (7,793,884)</b>	<b>\$ (11,247,787)</b>
Foreign currency translation adjustments	\$ (7,917)	\$ (27,485)	\$ (296)	\$ (41,231)
<b>Comprehensive loss</b>	<b>\$ (4,749,961)</b>	<b>\$ (3,609,655)</b>	<b>\$ (7,794,180)</b>	<b>\$ (11,289,018)</b>
Loss per common share - basic and diluted	\$ (0.29)	\$ (0.32)	\$ (0.57)	\$ (1.13)
Weighted average number of common shares outstanding:				
Basic and diluted	16,105,252	11,422,161	13,776,643	10,031,249

See accompanying notes to interim consolidated financial statements.

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

**Three Months Ended June 30, 2019**

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<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>
Stock-based compensation	—	—	111,351	—	—	111,351
Issuance of common stock via public offering, net	5,261,250	525	5,151,177	—	—	5,151,702
Deemed dividend from trigger of down round provision	—	—	789,594	—	(789,594)	—
Net loss	—	—	—	—	(3,952,450)	(3,952,450)
Foreign currency translation adjustments	—	—	—	(7,917)	—	(7,917)
<b>Balance at June 30, 2019</b>	<b>16,683,411</b>	<b>\$ 1,668</b>	<b>\$ 41,942,062</b>	<b>\$ (97,024)</b>	<b>\$ (36,763,651)</b>	<b>\$ 5,083,055</b>

**Six Months Ended June 30, 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	—	—	209,319	—	—	209,319
Issuance of common stock via public offering, net	5,261,250	525	5,151,177	—	—	5,151,702
Deemed dividend from trigger of down round provision	—	—	789,594	—	(789,594)	—
Net loss	—	—	—	—	(7,004,290)	(7,004,290)
Foreign currency translation adjustments	—	—	—	(296)	—	(296)
<b>Balance at June 30, 2019</b>	<b>16,683,411</b>	<b>\$ 1,668</b>	<b>\$ 41,942,062</b>	<b>\$ (97,024)</b>	<b>\$ (36,763,651)</b>	<b>\$ 5,083,055</b>

See accompanying notes to interim consolidated financial statements.

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

**Three Months Ended June 30, 2018**

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balance at March 31, 2018</b>	<b>11,422,161</b>	<b>\$ 1,142</b>	<b>\$ 35,747,609</b>	<b>\$ (31,826)</b>	<b>\$ (19,896,570)</b>	<b>\$ 15,820,356</b>
Stock-based compensation	—	—	9,423	—	—	9,423
Public offering costs	—	—	(2,160)	—	—	(2,160)
Net loss	—	—	—	—	(3,582,170)	(3,582,170)
Foreign currency translation adjustments	—	—	—	(27,485)	—	(27,485)
<b>Balance at June 30, 2018</b>	<b>11,422,161</b>	<b>\$ 1,142</b>	<b>\$ 35,754,872</b>	<b>\$ (59,311)</b>	<b>\$ (23,478,740)</b>	<b>\$ 12,217,963</b>

**Six Months Ended June 30, 2018**

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balance at December 31, 2017</b>	<b>6,047,161</b>	<b>\$ 605</b>	<b>\$ 25,541,210</b>	<b>\$ (18,080)</b>	<b>\$ (12,230,953)</b>	<b>\$ 13,292,782</b>
Stock-based compensation	—	—	18,547	—	—	18,547
Issuance of common stock	375,000	37	1,037,727	—	—	1,037,764
Net proceeds from issuance of common stock and warrants	5,000,000	500	9,157,388	—	—	9,157,888
Net loss	—	—	—	—	(11,247,787)	(11,247,787)
Foreign currency translation adjustments	—	—	—	(41,231)	—	(41,231)
<b>Balance at June 30, 2018</b>	<b>11,422,161</b>	<b>\$ 1,142</b>	<b>\$ 35,754,872</b>	<b>\$ (59,311)</b>	<b>\$ (23,478,740)</b>	<b>\$ 12,217,963</b>

See accompanying notes to interim consolidated financial statements.



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

	Six months ended June 30,	
	2019	2018
<b>Operating activities:</b>		
Net loss	\$ (7,004,290)	\$ (11,247,787)
<b>Non-cash adjustments reconciling net loss to operating cash flows:</b>		
Depreciation	2,315	288
Stock-based compensation	209,319	18,547
Non-cash lease expenses	10,549	—
Acquired in-process research and development	—	452,000
Impairment of goodwill	—	5,187,519
<b>Changes in operating assets and liabilities:</b>		
Other receivables	(461,982)	259,562
Prepaid expenses	(34,861)	(35,838)
Other current assets	—	193,495
Other non-current assets	79,063	66,160
Accounts payable	172,413	9,739
Accrued expenses	710,459	288,846
Other liabilities	(9,711)	(75)
<b>Net cash used in operating activities</b>	<b>(6,326,726)</b>	<b>(4,807,544)</b>
<b>Investing activities:</b>		
Purchases of property and equipment	—	(8,200)
Acquisition of Pear Tree and Hydra asset	—	(452,000)
<b>Net cash used in investing activities</b>	<b>—</b>	<b>(460,200)</b>
<b>Financing activities:</b>		
Net proceeds from issuance of common stock and warrants	5,151,702	10,195,653
<b>Net cash provided by financing activities</b>	<b>5,151,702</b>	<b>10,195,653</b>
Effect of exchange rate changes on cash and cash equivalents	(296)	(41,231)
<b>Net change in cash and cash equivalents</b>	<b>(1,175,320)</b>	<b>4,886,678</b>
Cash and cash equivalents, beginning of period	6,805,889	7,559,846
<b>Cash and cash equivalents, end of period</b>	<b>\$ 5,630,569</b>	<b>\$ 12,446,524</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	—
Deemed dividend from trigger of down round provision	\$ 789,594	—

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 advancement 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 differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. The Company's business strategy is to license or otherwise acquire the rights to differentiated product candidates in women's health, 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.

The Company has assembled a portfolio of clinical-stage and pre-clinical-stage candidates addressing unmet needs in women's health. The Company's portfolio includes these six clinical-stage candidates:

- DARE-BV1, a novel solution-to-gel formulation containing clindamycin phosphate 2% to treat bacterial vaginosis, or BV;
- Ovaprene, a non-hormonal monthly contraceptive intravaginal ring;
- Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder, or FSAD;
- DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy 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, or IVF, treatment plan.

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

- ORB-204 and ORB-214, 6-month and 12-month formulations of injectable etonogestrel for contraception;
- DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- DARE-OAB1, an intravaginal ring containing oxybutynin for the treatment of overactive bladder.

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. We expect that the bulk of our development expenses over the next two years will support the advancement of our clinical-stage product candidates.

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, competition from larger companies with recognized brands, greater capital resources and higher levels of dedicated staff, and compliance with government regulations, protection of proprietary technology, dependence on third parties, and product liability.

## **2. GOING CONCERN**

The Company has prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, as of June 30, 2019, the Company had an accumulated deficit of approximately \$36.8 million and had cash and cash equivalents of approximately \$5.6 million. The Company also had negative cash flow from operations of approximately \$6.3 million during the six months ended June 30, 2019.

In March of 2019, the Company announced that it received a second Notice of Award for an additional \$982,851 of the anticipated \$1.9 million from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or the NIH Grant, which is being applied to the clinical development efforts supporting Oviprene. As of June 30, 2019, the Company recorded a receivable in the amount of \$456,484 for expenses eligible for reimbursement under the NIH Grant that were incurred through June 30, 2019. See Note 9, "Grant Award," herein.

In April of 2019, the Company completed a sale of common stock raising net proceeds of approximately \$5.2 million. See Note 6, "Stockholders' Equity," herein. The Company needs to raise additional capital to continue to fund its operations and to successfully execute its current operating plan, including the development of its current product candidates.

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 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

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.

The Company believes that its current available cash resources will be sufficient to fund planned operations into the first quarter of 2020. For the foreseeable future, the Company's ability to continue its operations will depend on its ability to obtain additional capital.

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 assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders. 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 interim consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The Company's significant accounting policies are described in Note 1 to the interim consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission, or SEC on April 1, 2019. Since the date of those consolidated financial statements, there have been no material changes to the Company's significant accounting policies, except 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, 2018.

#### ***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.

Cash and cash equivalents of \$5.6 million and \$6.8 million are measured at fair value as of June 30, 2019 and December 31, 2018, respectively, and are classified within Level 1 of the fair value hierarchy. Other receivables are financial assets with carrying values that approximate fair value due to the short-term nature of these assets. Accounts payable and accrued expenses and other liabilities are financial liabilities with carrying values that approximate fair value due to the short-term nature of these liabilities.

## **Recently Adopted Accounting Standards**

In May 2014, FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, which impacts the way in which some entities recognize revenue for certain types of transactions. The new standard became effective beginning in 2018 for public companies. Because the Company does not currently have any contracts with customers, the Company's adoption of this accounting standard did not impact the Company's interim consolidated financial statements.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. The new standard is effective for public companies for fiscal years beginning after December 15, 2018, with early adoption permitted. ASU 2016-02 became effective for the Company on January 1, 2019 and was adopted using a modified retrospective approach and the effective date is as of the initial application. Consequently, financial information was not updated, and the disclosures required under ASU 2016-02 are not provided for dates and periods prior to January 1, 2019. ASU 2016-02 provides a number of optional practical expedients and accounting policy elections. The Company elected the package of practical expedients requiring no reassessment of whether any expired or existing contracts are or contain leases, the lease classification of any expired or existing leases, or initial direct costs for any existing leases. The Company recorded approximately \$232,000 right-of-use assets and \$241,000 lease liabilities related to its lease of office space as of the adoption date in the consolidated balance sheets. There are no changes to the statement of operations or cash flows as a result of the adoption.

In January 2017, FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which intended to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard became effective for the Company on January 1, 2018. The Company's early adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements relating to the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of income is required to be filed. This final rule was effective November 5, 2018. In accordance with the new rule, the Company added a Consolidated Statement of Stockholders' Equity in this report and elected to present a reconciliation in a single statement that shows the changes in stockholders' equity for each interim period, as well as each comparable period.

## **4. ACQUISITIONS**

### ***Cerulean/Private Daré Stock Purchase Transaction***

In July 2017, the Company completed its business combination with Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, in which Private Daré stockholders sold their shares to the Company in exchange for newly issued shares of the Company's common stock, and as a result, Private Daré became a wholly owned subsidiary of the Company and the Private Daré stockholders became majority stockholders of the Company. In connection with the closing of that transaction, the Company changed its name from "Cerulean Pharma Inc." to "Daré Bioscience, Inc." In this report, that transaction is referred to as the Cerulean/Private Daré stock purchase transaction and "Cerulean" refers to Cerulean Pharma Inc. before that transaction closed.

The Cerulean/Private Daré stock purchase transaction was accounted for as a reverse merger under the acquisition method of accounting whereby Private Daré was considered to have acquired Cerulean for financial reporting purposes. Pursuant to business combination accounting, the Company applied the acquisition method, which requires the assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The excess of

the purchase price over the assets acquired and liabilities assumed represents goodwill. The goodwill was primarily attributable to the cash and cash equivalents at closing of the transaction of approximately \$9.9 million and the impact of the unamortized fair value of stock options granted by Cerulean that were outstanding immediately before the transaction closed of approximately \$3.7 million.

The Company tests its goodwill for impairment at least annually as of December 31 and between annual tests if it becomes aware of an event or change in circumstance that would indicate the carrying value may be impaired. The Company tests goodwill for impairment at the entity level because it operates on the basis of a single reporting unit. A goodwill impairment is the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. When impaired, the carrying value of goodwill is written down to fair value. Any excess of the reporting unit goodwill carrying value over the fair value is recognized as impairment loss.

The Company assessed goodwill at March 31, 2018, determined there was an impairment and recognized an impairment charge of approximately \$5.2 million in the interim consolidated statement of operations and comprehensive loss for the three months ended March 31, 2018. As of March 31, 2018, the goodwill carrying value on the Company's consolidated balance sheet was written off in its entirety.

### ***Pear Tree Merger***

On April 30, 2018, the Company entered into an Agreement and Plan of Merger, the Merger Agreement, with Pear Tree Pharmaceuticals, Inc., or Pear Tree, Daré Merger Sub, Inc., a wholly-owned subsidiary of the Company, or Merger Sub, and two individuals in their respective capacities as Pear Tree stockholders' representatives. The transactions contemplated by the Merger Agreement closed on May 16, 2018, and as a result, Pear Tree became the Company's wholly owned subsidiary. 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.

The Company determined that the acquisition of Pear Tree should be accounted for as an asset acquisition instead of a business combination because substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, and therefore, the asset is not considered a business. Transaction costs of approximately \$452,000 associated with the merger were included in the Company's research and development expense.

Under the Merger Agreement, certain former and continuing Pear Tree service providers and former holders of Pear Tree's capital stock, or the Holders, were eligible to receive a \$75,000 payment due on the one-year anniversary of the closing of the merger and are eligible to receive tiered royalties, subject to 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. The Company must also make contingent payments to the Holders 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.

In accordance with the terms of the Merger Agreement, because the Negative Consideration Amount (as defined below) exceeded the Positive Consideration Amount (as defined below), at the time of the closing of the merger, the excess amount (approximately \$132,000) offset the \$75,000 payment due on the one-year anniversary of the closing of the merger and the balance will offset future payments otherwise due under the Merger Agreement to the Holders. Positive Consideration Amount means the sum of \$75,000, and the cash and cash equivalents held by Pear Tree at closing, and Negative Consideration Amount means the sum of (i) certain Pear Tree indebtedness and transaction expenses, (ii) transaction expenses of the stockholders' representatives, and (iii) amounts payable under Pear Tree's management incentive plan.

## **5. STOCK-BASED COMPENSATION**

### ***The 2015 Employee, Director and Consultant Equity Incentive Plan***

Prior to the Cerulean/Private Daré stock purchase transaction, Private Daré maintained the 2015 Employee, Director and Consultant Equity Incentive Plan, or the 2015 Private Daré Plan. Upon closing of the Cerulean/Private Daré stock purchase transaction, the Company assumed 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 Cerulean/Private Daré stock purchase 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, all of which were outstanding as of June 30, 2019, and 223,295 restricted shares of the Company's common stock. Those options are fully vested and expire in December 2025.

No further awards may be granted under the 2015 Private Daré Plan following the closing of the Cerulean/Private Daré stock purchase 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 six months ended June 30, 2019 or June 30, 2018.

### Amended and Restated 2014 Stock Incentive Plan

The Company maintains the Amended and Restated 2014 Plan, or the Amended 2014 Plan. 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, 2019, the number of authorized shares increased by 456,886 to 2,503,771, which increase represented 4% of the number of outstanding shares of common stock on such date.

### Summary of Stock Option Activity

The table below summarizes stock option activity under the Amended 2014 Plan, and related information for the six months ended June 30, 2019. The exercise price of all options granted during the six months ended June 30, 2019 was equal to the market value of the Company's common stock on the date of the grant. As of June 30, 2019, unamortized stock-based compensation expense of \$1,348,159 will be amortized over a weighted average period of 2.9 years. At June 30, 2019, 497,032 shares of common stock were reserved for future issuance under the Amended 2014 Plan.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2018 (1)	1,635,790	\$ 11.08
Granted	698,000	0.79
Exercised	—	—
Canceled/forfeited	(316,832)	24.55
Expired	(70)	59.48
Outstanding at June 30, 2019 (unaudited) (1)	2,016,888	\$ 5.40
Exercisable at June 30, 2019 (unaudited)	427,702	\$ 21.83

(1) Includes 10,149 shares subject to options granted under the 2015 Private Daré Plan assumed in connection with the Cerulean/Private Daré stock purchase transaction.

### 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	\$ 26,996	\$ —	\$ 51,699	\$ —
General and administrative	84,355	9,423	157,620	18,547
Total	\$ 111,351	\$ 9,423	\$ 209,319	\$ 18,547

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the six months ended June 30, 2019 are as follows:

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Expected life in years	10.0	10.0
Risk-free interest rate	2.09%	2.58%
Expected volatility	123%	121%
Forfeiture rate	0.0%	0.0%
Dividend yield	0.0%	0.0%
Weighted-average fair value of options granted	\$0.86	\$0.75

## 6. STOCKHOLDERS' EQUITY

### ***ATM Sales Agreement***

In January 2018, the Company entered into a common stock sales agreement under which the Company may sell up to an aggregate of \$10 million in gross proceeds through the sale of shares of 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. This 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.

The Company sold no shares under this agreement during either the three or six months ended June 30, 2019 or the three months ended June 30, 2018. During the six months ended June 30, 2018, the Company sold an aggregate of 375,000 shares common stock under this agreement for gross proceeds of approximately \$1.1 million and incurred issuance costs of \$237,403.

### ***February 2018 Underwritten Public Offering***

In February 2018, the Company closed an underwritten public offering of 5.0 million shares of its common stock and warrants to purchase up to 3.5 million shares of its common stock. Each share of common stock was sold with a warrant to purchase up to 0.70 of a share of the Company's common stock. The Company granted the underwriter a 30-day over-allotment option to purchase up to an additional 750,000 shares of common stock and/or warrants to purchase up to 525,000 shares of common stock. The underwriter exercised the option with respect to warrants to purchase 220,500 shares of common stock. The Company received gross proceeds of \$10.3 million, including the proceeds from the sale of the warrants upon exercise of the underwriter's over-allotment option, and net proceeds of approximately \$9.4 million.

### ***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 securities for a consideration per share less than a price equal to 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.



On April 11, 2019, in accordance with the anti-dilution provision of these warrants and as a result of the sale of shares in the public offering that closed on that date and which is discussed below, the exercise price of these warrants was automatically reduced to \$0.98 per share. For the three and six months ended June 30, 2019 the Company recorded \$0.8 million to additional paid in capital as a result of the triggering of the anti-dilution provisions.

In addition to the warrants issued in the February 2018 underwritten offering, as of June 30, 2019, there are outstanding warrants to purchase 30,333 shares of the Company's common stock, which are further described in the table below.

No warrants were exercised during the six months ended June 30, 2019 or 2018. As of June 30, 2019, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
2,906	\$	120.40	December 1, 2021
3,737	\$	120.40	December 6, 2021
17,190	\$	60.50	January 8, 2020
6,500	\$	10.00	April 4, 2026
3,720,500	\$	0.98	February 15, 2023
3,750,833			

#### **April 2019 Underwritten Public Offering**

On April 11, 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.

#### **7. LEASED PROPERTIES**

Effective January 1, 2019, the Company adopted ASC 842, which requires recognition of a right-of-use asset and lease liability for all leases at the commencement date based on the present value of lease payments over the lease term. Additional qualitative and quantitative disclosures regarding the Company's leasing arrangements are also required. The Company adopted ASC 842 prospectively and elected the package of transition practical expedients that does not require reassessment of: (1) whether any existing or expired contracts are or contain leases, (2) lease classification and (3) initial direct costs. In addition, the Company has elected other available practical expedients to not separate lease and nonlease components, which consist principally of common area maintenance charges, for all classes of underlying assets and to exclude leases with an initial term of 12 months or less.

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018, has term of 37 months, and terminates on July 31, 2021. The Company has the option to extend the term of the lease for one year at the Company's discretion. The gross monthly base rent is \$8,873, which increases approximately 4% per year, subject to certain future adjustments. The base rent was abated during the second month of the lease. 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 lease does not require material variable lease payments, a residual value guarantee or restrictive covenants. This is the Company's only lease.

The lease does 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 used an incremental borrowing rate of 7% as of January 1, 2019 for the operating lease that commenced prior to that date. The depreciable lives of operating lease assets and leasehold improvements are limited by the expected lease term.

As of June 30, 2019, the Company recorded a right of use asset of \$193,399 in other non-current assets, and \$87,859 and \$116,089, respectively, in current and non-current other liabilities on the consolidated balance sheet.

As of June 30, 2019, future minimum lease payments for the Company's corporate headquarters are:

Years ending December 31:

Remainder of 2019	\$	55,531
2020		112,943
2021		67,595
<b>Total future minimum lease payments</b>		<b>236,069</b>
Less: Difference between future minimum lease payments and discounted operating lease liabilities		42,669
<b>Total operating lease liabilities</b>	<b>\$</b>	<b>193,400</b>

Operating lease costs were \$27,038 and \$54,076 for the three and six months ended June 30, 2019, respectively. Operating lease costs are included in general and administrative expenses in the condensed consolidated statement of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were \$26,620 and \$53,240 for the three and six months ended June 30, 2019, respectively, and these amounts are included in operating activities in the condensed consolidated statements of cash flows.

## 8. COMMITMENTS AND CONTINGENCIES

### License and Research Agreements

#### *ADVA-Tec License Agreement*

In March 2017, the Company entered into a license agreement, or the ADVA-Tec License Agreement, with ADVA-Tec, Inc., or ADVA-Tec, under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. ADVA-Tec and its affiliates own issued patents or patent applications covering Ovaprene and control proprietary trade secrets covering the manufacture of Ovaprene. As of the date of this report, this patent portfolio includes nine issued U.S. patents and one pending U.S. patent application, and 59 granted patents and four pending patent applications in other major markets, all of which are exclusively licensed to the Company for the human contraceptive use of Ovaprene as a human contraceptive device. Under the terms of the ADVA-Tec Agreement, the Company has a right of first refusal to license these patents and patent applications for additional indications.

The following is a summary of other terms of the ADVA-Tec License Agreement:

*Research and Development.* ADVA-Tec will conduct certain research and development work as necessary to allow the Company to seek a Premarket Approval, or PMA, from the United States Food and Drug Administration, or the FDA, and will supply the Company with its requirements of Ovaprene for clinical and commercial use on commercially reasonable terms. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, such amounts totaling \$5.0 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

*Milestone Payments.* The Company will pay 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 million in the aggregate based on the achievement of certain worldwide net sales milestones. The development and regulatory milestones include: the completion of a successful postcoital clinical study, which is required before the Company can commence a Phase 3 pivotal human clinical trial; approval by the FDA to commence such Phase 3 pivotal human clinical trial; successful completion of such Phase 3 pivotal human clinical trial; the FDA's acceptance of a PMA filing for Ovaprene; the FDA's approval of the PMA for Ovaprene; obtaining Conformité Européenne Marking of Ovaprene in at least three designated European countries; obtaining regulatory approval in at least three designated European countries; and obtaining regulatory approval in Japan. Because these milestone payments depend upon the successful progress of

the Company's product development programs, the Company cannot estimate with certainty when these payments will occur, if ever.

For products currently in development, future potential milestone payments based on product development are approximately \$14.6 million as of June 30, 2019. Future potential milestone payments related to commercialization totaled \$20 million at June 30, 2019. The Company is unable to estimate with certainty the timing on when these milestone payments will occur as these payments depend on the Company's product development programs.

**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. The Company is unable to estimate with certainty the timing on when these royalty payments will occur as these payments depend on the Company's product development programs.

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

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

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

The following is a summary of other terms of the SST License 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 SST License 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 SST License 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 SST License Agreement.

**Royalty Payments.** SST will be eligible to receive (1) 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 (2) 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 and \$100 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.

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

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

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

In March 2018, the Company entered into an exclusive development and option agreement, or the Orbis 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 the Orbis Agreement, the Company paid Orbis \$300,000 to conduct the first stage of development work, Stage 1, as follows: \$150,000 upon signing the Orbis Agreement, \$75,000 at the 50% completion point, not later than 6 months following the date the Orbis 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 Orbis 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 Orbis Agreement provides the Company with an option to enter into a license agreement for ORB-204 and ORB-214 should development efforts be successful.

### **Juniper Pharmaceuticals - License Agreement**

In April 2018, the Company entered into an Exclusive License Agreement, or the Juniper License Agreement, with Juniper Pharmaceuticals, Inc., or Juniper, under which Juniper granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Juniper, 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 Juniper 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 the Juniper License Agreement.

The following is a summary of certain terms of the Juniper License Agreement:

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

**Annual Maintenance Fee.** The Company will pay an annual license maintenance fee to Juniper on each anniversary of the date of the Juniper License 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 Juniper 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 Juniper License Agreement.

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

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

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

#### **Pear Tree Acquisition**

The Company may be required to make certain royalty and milestone payments under the Merger Agreement (see Note 4).

#### **Hammock/MilanaPharm Assignment and License Agreement**

On December 5, 2018, the Company entered into (a) an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and (b) a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, the Company acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In DARE-BV1, this proprietary technology is formulated with clindamycin, 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.

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

**License Fees.** The Company paid \$25,000 to MilanaPharm in connection with the execution of the License Amendment and must pay \$200,000 to MilanaPharm (in the Company's discretion, either in cash or with shares of the Company's common stock) within 15 days of the first to occur of December 5, 2019 or the closing of an equity financing in which the Company raises aggregate proceeds of at least \$10.0 million.

*Milestone Payments.* The Company will pay to MilanaPharm (1) up to \$300,000 in the aggregate upon achievement of certain 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.* During the royalty term, the Company will pay MilanaPharm high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes. The royalty term, which is determined on a country-by-country basis and licensed product-by-product basis (or process-by-process basis), begins with the first commercial sale of a licensed product or process in a country and terminates on the latest of (a) the expiration date of the last valid claim of the licensed patent rights that cover the method of use of such product or process in such country, or (b) 10 years following the first commercial sale of such product or process in such country. Royalty payments are subject to reduction in certain circumstances, including as a result of generic competition, patent prosecution expenses incurred by the Company, or payments to third parties for rights or know-how that are required for the Company to exercise the licenses granted to it under the MilanaPharm License Agreement or that are strategically important or could add value to a licensed product or process in a manner expected to materially generate or increase sales.

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

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

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

*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 \$250,000 to Hammock in connection with the execution of the Assignment Agreement and must pay \$250,000 to Hammock (in the Company's discretion either in cash or with shares of the Company's common stock) within 15 days of the first to occur of December 5, 2019 or the closing of an equity financing in which the Company raises aggregate proceeds of at least \$10.0 million.

*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 payments described above, including the milestone payments.

## 9. GRANT AWARD

In April 2018, the Company received a Notice of Award for the first \$224,665 of the anticipated \$1.9 million in grant funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a division of the National Institutes of Health, or the NIH. The Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment. The Company received all \$224,665 of the award payments under this Notice of Award. Such payments were applied to clinical development efforts supporting Ovaprene and were recognized in the statement of operations as a reduction to research and development activities as the related costs were incurred to meet those obligations over the period.

On March 11, 2019, the Company received a second Notice of Award for an additional \$982,851 of the anticipated \$1.9 million in grant funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. The second award followed the NIH's review of an interim data analysis and other results of the first phase of the research supporting Ovaprene. Award payments under this second notice of award (\$161,007 received through June 30, 2019) are being applied to clinical development efforts supporting Ovaprene. At June 30, 2019, the Company recorded a receivable of \$456,484 for expenses incurred through such date that are eligible for reimbursement under this second notice of award.

The remaining portion of the award under the grant, \$730,722, is contingent upon, among other matters, assessment that the results of the ongoing Ovaprene study satisfy specified requirements set out in the award notice, and the availability of funds.

## 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock options	2,190,360	547,571	2,190,360	547,571
Warrants	3,750,833	3,751,002	3,750,833	3,751,002
Total	5,941,193	4,298,573	5,941,193	4,298,573

## 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, 2018 included in our Annual Report on Form 10-K for the year ended December 31, 2018, or our 2018 10-K, filed with the Securities and Exchange Commission, or SEC, on April 1, 2019. 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 2018 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 advancement of innovative products for women's health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. Our business strategy is to 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. 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 addressing unmet needs in women's health. Our portfolio includes these six clinical-stage product candidates:

- DARE-BV1, a novel solution-to-gel formulation containing clindamycin phosphate 2% for bacterial vaginosis, or BV;
- Ovaprene®, a non-hormonal monthly contraceptive intravaginal ring;
- Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil for female sexual arousal disorder, or FSAD;
- DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for 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;
- DARE-FRT1, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an IVF treatment plan; and

Our portfolio also includes these pre-clinical stage product candidates:

DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel;



- ORB-204 and ORB-214, 6-month and 12-month formulations of injectable etonogestrel for contraception; and
- DARE-OAB1, an intravaginal ring containing oxybutynin for the treatment of overactive bladder.

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 bulk of our development expenses over the next two years will support the advancement of our clinical-stage product candidates.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any revenue. We are subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key 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.

### **Clinical Stage Product Candidates**

The following provides a brief overview of the clinical stage product candidates on which we are primarily focusing our development efforts at this time.

#### *DARE-BV1*

DARE-BV1 is a novel solution-to-gel formulation containing clindamycin, an antibiotic used to treat certain bacterial infections, including BV. DARE-BV1 is designed to be administered in a convenient, single vaginal dose with a dual release pattern to prolong the duration of exposure to clindamycin at the site of infection and to potentially improve the rate of effectiveness compared to existing FDA-approved therapies. Current FDA-approved therapies for BV have clinical cure rates of less than 70 percent. In an investigator initiated proof-of-concept study that enrolled 30 women, DARE-BV1 demonstrated an 86 percent clinical cure rate in evaluable subjects (n=26) at the test-of-cure visit (Day 7-14) after one administration. We plan to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-BV1 for BV in the U.S.

In August 2019, the FDA granted DARE-BV1 Qualified Infectious Disease Product (QIDP) designation for the treatment of BV in women. QIDP designation is available under Title VIII of the FDA Safety and Innovation Act, titled General Antibiotic Incentive Now (GAIN), which creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The primary incentive is a five-year exclusivity extension added to any exclusivity for which a QIDP qualifies upon FDA approval. Additionally, DARE BV-1's QIDP designation makes it eligible for Fast Track designation and Priority Review.

We expect to commence a Phase 3 clinical study of DARE-BV1 in approximately 250 women in the fourth quarter of 2019 and, if the study is successful, to be in a position to file a new drug application, or NDA, with the FDA in 2020. We anticipate that the cost of the Phase 3 clinical study, including manufacturing activities, and the NDA filing thereafter to be less than \$10.0 million.

#### Ovaprene

Ovaprene is an intravaginal ring that, if approved, would represent a new category of birth control. Ovaprene does not contain hormones and is designed to be worn conveniently over multiple weeks and to require no intervention at the time of intercourse. Ovaprene is a silicone-reinforced ring with a soft, absorbable scaffolding that encircles a fluid-permeable barrier. A polymer matrix in the center of the ring functions as a physical barrier to sperm. The silicone ring also releases ferrous gluconate to create a spermistatic environment within the vagina.

Ovaprene is a combination product and, following a request for designation process, the FDA designated Center for Devices and Radiological Health, or CDRH, as the lead agency FDA program center for premarket review and product regulation. CDRH has determined that a PMA will be required to market Ovaprene in the U.S.

In May 2018, we announced initiation of a postcoital test, or PCT, clinical trial of Ovaprene and in July 2019 we announced that we completed recruitment. This ongoing clinical trial is designed to assess general safety, acceptability, and effectiveness in preventing progressively motile sperm, or PMS, from reaching the cervical canal following intercourse. The study will enroll approximately 50 couples, with the woman to be evaluated over the course of five menstrual cycles, with a target of having approximately 25 women complete a total of 21 visits. Each woman's cervical mucus will be measured at several points during the study, including a baseline measurement at menstrual cycle 1 that excludes the use of any product. Subsequent cycles and visits will include the use of a diaphragm (menstrual cycle 2) and Ovaprene (menstrual cycles 3, 4 and 5). Topline data from the PCT clinical trial are expected to be available in the fourth quarter of 2019.

PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness. Infertility research suggests that higher rates of pregnancy are associated with PMS per high power field, or HPF, of from greater than one to greater than 20 sperm, and less than 5 PMS per HPF is considered reflective of contraceptive effectiveness.

If the PCT clinical trial demonstrates that less than 5 PMS per HPF progressed into the cervical canal in most women and that Ovaprene can be safely worn over multiple weeks, we intend to prepare and file an Investigational Device Exemption, or IDE, with the FDA to commence a pivotal clinical trial to support marketing approvals of Ovaprene in the United States, Europe and other countries worldwide.

#### *Sildenafil Cream, 3.6%*

Sildenafil Cream, 3.6%, which incorporates sildenafil, the same active ingredient in the male erectile dysfunction drug Viagra®, if approved, could be the first FDA-approved FSAD treatment option for women. FSAD is characterized primarily by a persistent or recurrent inability to attain or maintain sufficient physical sexual arousal, frequently resulting in distress or interpersonal difficulty. Sildenafil Cream, 3.6% is formulated to increase blood flow locally to the vulvar-vaginal tissue, leading to a potential improvement in genital arousal response.

We plan to leverage the existing data and established safety profile of sildenafil and the Viagra® brand to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of Sildenafil Cream, 3.6% in the U.S. During the third quarter of 2018, we had a Type C meeting with the FDA regarding the design of our Phase 2b clinical trial for Sildenafil Cream, 3.6% and the overall development program for this product candidate. Based on the FDA guidance we received from that meeting, we commenced Phase 2b related activities during the fourth quarter of 2018 with the initiation of a non-interventional content validity study intended to support the validity of specific patient reported outcome, or PRO, measures. This study seeks to identify and document the genital arousal symptoms that will be assessed in our planned at-home Phase 2b trial, as well as our Phase 3 studies, and to demonstrate that these symptoms are the most important and relevant to our target population and are also acceptable endpoints for the FDA. We are in the final stages of completing this study. We believe that completing this study will be a significant de-risking event for our Sildenafil Cream, 3.6% program because it will position us to hold a Type C meeting with the FDA to review the study's findings and to obtain the FDA's guidance on the endpoints for our Phase 2b and Phase 3 clinical trials, including whether the FDA agrees that the PRO instruments are content valid for the target population. Our plan is for the endpoints used in the Phase 2b trial to reflect the endpoints used in the Phase 3 trial. The timing of when we initiate the Phase 2b at-home trial will be influenced by the FDA's guidance. We continue to explore additional clinical and non-clinical work that might be valuable or required to support the overall program and anticipated design of the Phase 2b trial.

#### DARE-HRT1

DARE-HRT1 is an intravaginal ring, or IVR, containing bio-identical estradiol and bio-identical progesterone to treat the vasomotor symptoms (VMS) associated with menopause as part of a hormone replacement therapy regimen. There are currently no FDA-approved IVRs that deliver bio-identical progesterone in combination with bio-identical estradiol. The IVR technology used in DARE-HRT1 was developed by Dr. Robert Langer from the Massachusetts Institute of Technology and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School. We plan to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-HRT1 in the U.S. We intend to initiate a Phase 1 clinical study for DARE-HRT1 during 2019 and to report topline results in 2020. DARE-HRT1 has the potential to be a first-in-class product.

## **Financial Overview**

We incurred a loss of approximately \$7.0 million for the six months ended June 30, 2019. As of June 30, 2019, we had (a) an accumulated deficit of approximately \$36.8 million and (b) cash and cash equivalents of approximately

\$5.6 million. We also had negative cash flow from operations of approximately \$6.3 million during the six months ended June 30, 2019. As further discussed below, in an underwritten public offering we closed in April 2019, we received aggregate net proceeds of approximately \$5.2 million. 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.

## **Recent Events**

### ***Underwritten Public Offering***

On April 11, 2019, we closed an underwritten public offering of 4,575,000 shares of our common stock at a public offering price of \$1.10 per share. We 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, we issued a total of 5,261,250 shares, and received gross proceeds of approximately \$5.8 million and net proceeds of approximately \$5.2 million after deducting underwriting discounts and offering expenses.

As a result of the sale of shares of our common stock in the offering described above, per the terms of the warrants we issued in February 2018, their exercise price was automatically reduced from \$3.00 to \$0.98 per share on April 11, 2019. For additional information, see Note 6 to our unaudited interim consolidated financial statements contained in this report.

## **Financial Operations Overview**

### ***Revenue***

To date we have not generated any revenue and do not expect to generate any revenue for the foreseeable future. In the future, we may generate revenue from product sales, license fees, milestone and research and development payments in connection with strategic partnerships, and royalties resulting from the sales of products developed under licenses of intellectual property. Our ability to generate product revenue will depend on the successful clinical development of our product candidates, receiving regulatory approvals to market such products and the eventual successful commercialization of product candidates. If we fail to complete the development of products 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 clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies;
- transaction costs related to the acquisition of technologies and related intellectual property; 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 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. 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 us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. 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 and Note 1 to our financial statements contained in our 2018 10-K and Note 3 to our unaudited interim consolidated financial statements contained in this report.

### **Results of Operations**

#### **Comparison of Three Months Ended June 30, 2019 and 2018 (Unaudited)**

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

	Three months ended June 30,		Dollar
	2019	2018	Change
Operating expenses:			
General and administrative expense	\$ 1,307,379	\$ 1,157,174	\$ 150,205
Research and development expenses	2,512,572	2,217,622	294,950
License expenses	162,500	250,000	(87,500)
Total operating expenses	3,982,451	3,624,796	357,655
Loss from operations	(3,982,451)	(3,624,796)	(357,655)
Other income	30,001	42,626	(12,625)
Net loss	(3,952,450)	(3,582,170)	(370,280)
Deemed dividend from trigger of down round provision feature	(789,594)	—	(789,594)
Net loss to common shareholders	(4,742,044)	(3,582,170)	(1,159,874)
Other comprehensive loss:			
Foreign currency translation adjustments	(7,917)	(27,485)	19,568
Comprehensive loss	\$ (4,749,961)	\$ (3,609,655)	\$ (1,140,306)

### **Revenues**

We did not recognize any revenues for either of the three months ended June 30, 2019 or 2018.

**General and administrative expenses**

The increase of \$150,205 in general and administrative expenses for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018 was primarily attributable to an increase in (i) personnel costs of approximately \$102,422 reflecting the hiring of additional employees which resulted in higher salary, benefit and bonus expenses in the current period, and (ii) an increase in stock-based compensation expense of \$74,932. Those increases were partially offset by a decrease of approximately \$53,612 in expenses for outside professional services in the current period as compared to the same period of the prior year.

**Research and development expenses**

The increase of \$294,950 in research and development expenses for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018 was primarily attributable to (i) an increase in costs related to development activities of approximately \$518,051 for Ovaprene and Sildenafil Cream, 3.6%, and to a lesser extent, for DARE-BV1 and DARE-HRT1, offset by grant funding recorded as a reduction to research and development expense related to Ovaprene of approximately \$456,484, (ii) an increase in personnel costs of approximately \$233,382 reflecting the hiring of additional employees which resulted in higher salary, benefit and bonus expenses, and (iii) an increase in stock-based compensation expense of \$26,996.

**License expenses**

The license expenses of \$162,500 for the three months ended June 30, 2019 related to (i) the accrual of \$112,500 of deferred license fees in the aggregate due under the Assignment Agreement with Hammock Pharmaceuticals, Inc. and the First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, and (ii) the \$50,000 annual license maintenance fee due under the Juniper License Agreement. During the quarter, we accrued (y) \$62,500 of the \$250,000 of license fees payable under the Assignment Agreement and (z) \$50,000 of the \$200,000 of license fees payable under the First Amendment to License Agreement. Both of these license fees are due in December 2019, and in our discretion, may be paid either in cash or with shares of our common stock.

The license expense of \$250,000 for the three months ended June 30, 2018 was entirely related to the \$250,000 non-creditable upfront license fee payment to Juniper in connection with the execution of the Juniper License Agreement.

For further discussion of these license fees, see Note 8 to our unaudited interim consolidated financial statements contained in this report.

**Other income**

The decrease of \$12,625 in other income for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018 was primarily due to interest earned on cash balances in the current period.

**Comparison of Six Months Ended June 30, 2019 and 2018 (Unaudited)**

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

	Six months ended June 30,		Dollar
	2019	2018	Change
<b>Operating expenses:</b>			
General and administrative expense	\$ 2,584,559	\$ 2,460,363	\$ 124,196
Research and development expenses	4,205,963	3,304,275	\$ 901,688
License expenses	275,000	350,000	\$ (75,000)
Impairment of goodwill	—	5,187,519	\$ (5,187,519)
Total operating expenses	7,065,522	11,302,157	\$ (4,236,635)
Loss from operations	(7,065,522)	(11,302,157)	(4,236,635)
Other income	61,232	54,370	\$ 6,862
Net loss	(7,004,290)	(11,247,787)	\$ 4,243,497
Deemed dividend from trigger of down round provision feature	(789,594)	—	789,594
Net loss to common shareholders	(7,793,884)	(11,247,787)	(3,453,903)
<b>Other comprehensive loss:</b>			
Foreign currency translation adjustments	(296)	(41,231)	\$ 40,935
Comprehensive loss	\$ (7,794,180)	\$ (11,289,018)	\$ 3,494,838

**Revenues**

We did not recognize any revenues for either of the six months ended June 30, 2019 or 2018.

**General and administrative expenses**

The increase of \$124,196 in general and administrative expenses for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018 was primarily attributable to an increase in (i) personnel costs of approximately \$344,028 reflecting the hiring of additional employees which resulted in higher salary, benefit and bonus expenses in the current period, and (ii) an increase in stock-based compensation expense of \$139,073. Those increases were partially offset by a decrease of approximately \$365,465 in expenses for outside professional services

**Research and development expenses**

The increase of \$901,688 in research and development expenses for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018 was primarily attributable to (i) an increase in costs related to development activities of approximately \$922,064 for Ovaprene and Sildenafil Cream, 3.6%, and to a lesser extent, for DARE-BV1 and DARE-HRT1, offset by grant funding recorded as a reduction to research and development expense related to Ovaprene of approximately \$617,491, (ii) an increase in personnel costs of approximately \$344,028 due to increased salary, benefit and bonus expenses due to staff additions, and (iii) an increase in stock-based compensation expense of \$51,699.

**License expenses**

The license expenses of \$275,000 for the six months ended June 30, 2019 related to (i) the accrual of deferred license fees due under the Assignment Agreement with Hammock Pharmaceuticals, Inc. and the First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC; and (ii) the \$50,000 annual license maintenance fee due under the Juniper License Agreement. During the six months ended June 30, 2019, we accrued (y) \$125,000 of the \$250,000 of license fees payable under the Assignment Agreement and (z) \$100,000 of the \$200,000 of license fees payable under the First Amendment to License Agreement. Both of these license fees are due in December 2019, and in our discretion, may be paid either in cash or with shares of our common stock

The license expenses of \$350,000 for the six months ended June 30, 2018 was related to the \$250,000 non-creditable upfront license fee payment to Juniper in connection with the execution of the Juniper License Agreement and to the \$100,000 in license fees paid to SST.

For further discussion of these license fees, see Note 8 to our unaudited interim consolidated financial statements contained in this report.

### ***Goodwill impairment expense***

We incurred an impairment loss of \$5,187,519 for the six months ended June 30, 2018 due to our determination that the carrying amount of our goodwill exceeded its estimated fair value at June 30, 2018. For a discussion of our goodwill analysis, see Note 4 to our unaudited interim consolidated financial statements contained in this report.

### ***Other income***

The increase of \$6,862 in other income for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018 was primarily due to interest earned on cash balances in the current period.

### **Liquidity and Capital Resources and Financial Condition**

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.

At June 30, 2019, our accumulated deficit was approximately \$36.8 million, our cash and cash equivalents were approximately \$5.6 million, our working capital was approximately \$4.6 million, and we had incurred a net loss from operations of \$7.1 million. We had negative cash flow from operations of approximately \$6.3 million during the six months ended June 30, 2019. We received gross proceeds of approximately \$5.8 million, and net proceeds of approximately \$5.2 million after deducting underwriting discounts and offering expenses, from our underwritten public offering that closed in April 2019. Considering our current cash resources, we believe our existing resources will be sufficient to fund planned operations into the first quarter of 2020. For the foreseeable future, our ability to continue our operations will depend upon our ability to obtain additional capital.

These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying interim consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

### ***Plan of Operations and Future Funding Requirements***

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 expect our expenses to increase during the rest of 2019 as we continue the development of our product candidates, including as we (1) complete the Ovaprene PCT clinical trial, (2) prepare for the initiation of a Phase 3 clinical trial of DARE-BV1, (3) continue Phase 2b-related activities and prepare for the potential commencement of the at-home Phase 2b clinical study of Sildenafil Cream, 3.6%, (4) prepare for the initiation of a Phase 1 clinical study of DARE-HRT1, and (5) to a lesser extent, continue to advance our other product candidates.

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 do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying 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 are 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. 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. See "ITEM 1A. RISK FACTORS—Risks Related to Our Business—*We will need to raise additional capital to continue our operations,*" in our 2018 10-K.

### Cash Flows

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

	Six months ended June 30,	
	2019	2018
Net cash used in operating activities	(6,326,726)	(4,807,544)
Net cash used in investing activities	—	(460,200)
Net cash provided by financing activities	5,151,702	10,195,653
Effect of exchange rate changes on cash and cash equivalents	(296)	(41,231)
Net increase (decrease) in cash	<u>\$ (1,175,320)</u>	<u>\$ 4,886,678</u>

### Net cash used in operating activities

Cash used in operating activities for the six months ended June 30, 2019 included the net loss of \$7,004,290, decreased by non-cash stock-based compensation expense of \$209,319. Major components reducing operating cash in this period were a \$461,982 increase in other receivables and a \$34,861 increase in prepaid expenses. Major components providing operating cash in this period were a \$710,459 increase in accrued expenses, a \$172,413 increase in accounts payable, and a \$79,063 increase in other non-current assets.

Cash used in operating activities for the six months ended June 30, 2018 included the net loss of \$11,247,787, decreased by non-cash impairment of goodwill of \$5,187,519, acquired in-process research and development expense of approximately \$452,000 and non-cash stock-based compensation expense of \$18,547. Major components providing operating cash in this period were a \$288,846 increase of accounts payable, a \$9,739 increase of accrued expenses, a \$259,562 decrease in other receivables and a \$193,495 decrease in other current assets.

### Net cash used in investing activities

No cash was provided by or used in investing activities for the six months ended June 30, 2019.

Cash used in investing activities for the six months ended June 30, 2018 consisted of approximately \$452,000 of transaction costs associated with our acquisition of Pear Tree and approximately \$8,200 related to the purchase of property and equipment.



**Net cash provided by financing activities**

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

Cash provided by financing activities for the six months ended June 30, 2018 consisted of proceeds from the underwritten public offering completed in February 2018 and sales under the at-the-market offering agreement in January and February 2018.

**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 8 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.

Based on 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, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of June 30, 2019 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 2018 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 2018 10-K other than as described below:

#### **Risks Related to Our Securities**

**There is no assurance that we will continue to satisfy the listing requirements of the Nasdaq Capital Market.**

Our common stock is listed on the Nasdaq Capital Market. As previously reported, on June 21, 2019, we received a letter from the Listing Qualifications Department (the "Nasdaq Staff") of the Nasdaq Stock Market ("Nasdaq") notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock was below the minimum \$1.00 per share requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"), and that we have until December 18, 2019 to regain compliance. We will regain compliance if the closing bid price of our common stock is at least \$1.00 for a minimum of 10 consecutive business days at any time between June 21, 2019 and December 18, 2019, unless the Nasdaq Staff exercises its discretion to extend such 10-day period. From June 21, 2019 through August 13, 2019, the closing bid price of our common stock has been less than \$1.00.

If we have not regained compliance by December 18, 2019, we may be eligible for an additional 180-day compliance period. To qualify for this additional compliance period, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, other than the Minimum Bid Price Requirement, including having stockholders' equity of at least \$5 million. In addition, we would also be required to notify Nasdaq of our intent to cure the minimum bid price deficiency during the additional compliance period, which may include, if necessary, implementing a reverse stock split. Our stockholders' equity at June 30, 2019 was \$5.1 million, and, as such, we expect that we will need to raise additional equity capital to be eligible for the additional compliance period. If our stockholders' equity is not at least \$5.0 million at September 30, 2019 but increases to at least \$5.0 million after September 30, 2019 and before December 18, 2019, we understand that the Nasdaq Staff has discretion whether to consider such increase for purposes of determining our eligibility for the additional compliance period. If we are not granted the additional compliance period for any reason, the Nasdaq Staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the Nasdaq Staff's delisting determination to a Nasdaq Hearing Panel.

There can be no assurance we will regain compliance with the Minimum Bid Price Requirement or continue to satisfy the other continued listing requirements of The Nasdaq Capital Market. The delisting of our common stock for whatever reason could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and could result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the delisting of our common stock for whatever reason may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

**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		
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

# Furnished herewith. This certification is being furnished solely to accompany this report pursuant to 18 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 in such filing.

## Signatures

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

Daré Bioscience, Inc.

Date: August 14, 2019

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

Date: August 14, 2019

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

## CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Daré Bioscience, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2019

/s/ Sabrina Martucci Johnson  
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: August 14, 2019

/s/ Lisa Walters-Hoffert

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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 June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2019

/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 June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2019

/s/ Lisa Walters-Hoffert

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Lisa Walters-Hoffert

Chief Financial Officer

(principal financial officer)