

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

(Mark One)

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

For the quarterly period ended **September 30, 2018**

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)

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

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

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

**92122**  
(Zip Code)

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

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 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 November 9, 2018, 11,422,161 shares of the Registrant's Common Stock, par value \$0.0001, were issued and outstanding.

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### 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 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 (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;*
  - Unsuccessful clinical trials 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 critical 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, market and distribute products;*
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- *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 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 our products to competition from other formulations using the same active ingredients.*
- *Higher risk of failure associated with product candidates in preclinical 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;*
- *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.*

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

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## PART I. FINANCIAL INFORMATION

## Item 1. Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries  
Consolidated Balance Sheets

	September 30, 2018 (unaudited)	December 31, 2017
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 9,537,463	\$ 7,559,846
Other receivables	80,278	284,206
Prepaid expenses	549,949	311,571
Other current assets	—	193,495
Total current assets	10,167,690	8,349,118
Property and equipment, net	10,572	—
Goodwill	—	5,187,519
Other non-current assets	617,499	723,191
Total assets	<u>\$ 10,795,761</u>	<u>\$ 14,259,828</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,202,912	\$ 966,653
Total current liabilities	1,202,912	966,653
Deferred rent	9,292	392
Total liabilities	1,212,204	967,045
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit)		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized		
None issued and outstanding	—	—
Common stock: \$0.0001 par value, 120,000,000 shares authorized, 11,422,161 and 6,047,161 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1,142	605
Accumulated other comprehensive loss	(78,032)	(18,080)
Additional paid-in capital	35,713,662	25,541,210
Accumulated deficit	(26,053,215)	(12,230,952)
Total stockholders' equity	9,583,557	13,292,783
<b>Total liabilities and stockholders' equity</b>	<u>\$ 10,795,761</u>	<u>\$ 14,259,828</u>

See accompanying notes to interim consolidated financial statements.

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses:				
General and administrative	\$ 1,175,049	\$ 1,052,628	\$ 3,635,413	\$ 1,729,338
Research and development expenses	1,446,548	280,793	4,750,823	312,169
License expenses	—	—	350,000	—
Impairment of goodwill	—	—	5,187,519	—
Total operating expenses	<u>2,621,597</u>	<u>1,333,421</u>	<u>13,923,755</u>	<u>2,041,507</u>
Loss from operations	(2,621,597)	(1,333,421)	(13,923,755)	(2,041,507)
Other income (expense)	47,122	(296,262)	101,492	(330,233)
Net loss	<u>\$ (2,574,475)</u>	<u>\$ (1,629,683)</u>	<u>\$ (13,822,263)</u>	<u>\$ (2,371,740)</u>
Foreign currency translation adjustments	\$ (18,721)	\$ (9,774)	\$ (59,952)	\$ (9,774)
Comprehensive loss	<u>\$ (2,593,196)</u>	<u>\$ (1,639,457)</u>	<u>\$ (13,882,215)</u>	<u>\$ (2,381,514)</u>
Loss per common share - basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.33)</u>	<u>\$ (1.32)</u>	<u>\$ (1.04)</u>
Weighted average number of common shares outstanding:				
Basic and diluted	<u>11,422,161</u>	<u>4,986,226</u>	<u>10,499,982</u>	<u>2,283,673</u>

See accompanying notes to interim consolidated financial statements.

The operations presented in the interim consolidated financial statements and accompanying notes (A) for the three and nine months ended September 30, 2018 and that include the period from July 19, 2017 to September 30, 2017 represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 4, "Acquisitions – Cerulean/Private Daré Stock Purchase Transaction," of the Notes to the Interim Consolidated Financial Statements (Unaudited) appearing in this report for a discussion of the Cerulean/Private Daré stock purchase transaction.

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

	Nine months ended September 30,	
	2018	2017
<b>Operating activities:</b>		
Net loss	\$ (13,822,263)	\$ (2,371,740)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,263	—
Stock-based compensation	58,538	6,953
Non-cash interest	—	316,804
Acquired in-process research and development	507,000	—
Impairment of goodwill	5,187,519	—
Changes in operating assets and liabilities, net impact of acquisition:		
Other receivables	203,928	—
Prepaid expenses	(238,378)	(224,433)
Other current assets	193,495	—
Other non-current assets and deferred charges	105,692	(2,800)
Accounts payable and accrued expenses	236,259	659,223
Interest payable	—	36,776
Deferred rent	8,900	157
Net cash used in operating activities	<u>(7,558,047)</u>	<u>(1,579,060)</u>
<b>Investing activities:</b>		
Cash acquired through merger	—	9,918,440
Purchases of property and equipment	(11,836)	—
Acquisition of Pear Tree and Hydra asset	(507,000)	—
Net cash provided by (used in) investing activities	<u>(518,836)</u>	<u>9,918,440</u>
<b>Financing activities:</b>		
Net proceeds from issuance of common stock and warrants	10,114,452	—
Proceeds from issuance of convertible promissory notes	—	155,000
Net cash provided by financing activities	<u>10,114,452</u>	<u>155,000</u>
Effect of exchange rate changes on cash and cash equivalents	(59,952)	(9,774)
Net change in cash and cash equivalents	1,977,617	8,484,606
Cash and cash equivalents, beginning of period	7,559,846	44,614
Cash and cash equivalents, end of period	<u>\$ 9,537,463</u>	<u>\$ 8,529,220</u>

See accompanying notes to interim consolidated financial statements.

The operations presented in the interim consolidated financial statements and accompanying notes (A) for the three and nine months ended September 30, 2018 and that include the period from July 19, 2017 to September 30, 2017 represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 4, "Acquisitions – Cerulean/Private Daré Stock Purchase Transaction," of the Notes to the Interim Consolidated Financial Statements (Unaudited) appearing in this report for a discussion of the Cerulean/Private Daré stock purchase transaction.

**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 reproductive health. Daré Bioscience, Inc. and its wholly owned subsidiaries, Daré Bioscience Operations, Inc., Daré Bioscience Australia Pty LTD, and Pear Tree Pharmaceuticals, Inc., 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 reproductive health product candidates, some of which have existing clinical proof-of-concept data, and to take those candidates through advanced stages of clinical development or regulatory approval.

The Company has assembled a portfolio of clinical-stage and preclinical-stage candidates addressing unmet needs in women's reproductive health. The Company's two clinical-stage assets—Ovaprene® and Sildenafil Cream, 3.6%—were obtained through product license and development agreements. Ovaprene, a non-hormonal monthly contraceptive candidate was licensed in July of 2017 and Sildenafil Cream, 3.6%, a potential treatment for Female Sexual Arousal Disorder was licensed in February of 2018. In March of 2018, the Company entered into a collaboration and option agreement covering new injectable contraceptive product candidates; in April of 2018, the Company licensed the worldwide rights to a portfolio of preclinical intravaginal rings; in May of 2018, the Company acquired a company that owns the rights to a proprietary vaginal tamoxifen tablet to treat vulvar and vaginal atrophy; and in July of 2018, the Company acquired certain assets related to a novel target for non-hormonal contraceptives for both men and women.

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 late-stage clinical development or regulatory approval.

The Company has not generated any revenue related to its primary business purpose to date and is subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key individuals, competition from other companies, the need to develop commercially viable products in a timely and cost-effective manner, and the need to obtain adequate additional capital to fund the development of product candidates. The Company is also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, and product liability.

**2. LIQUIDITY**

The Company has a history of losses from operations and anticipates that it will continue to incur losses for at least the next several years. For the nine months ended September 30, 2018, the Company incurred a net loss of \$13.8 million. At September 30, 2018, the Company had an accumulated deficit of approximately \$26.1 million and had cash and cash equivalents of approximately \$9.5 million. The Company also had negative cash flow from operations of approximately \$7.6 million during the nine months ended September 30, 2018.

During the first quarter of 2018, the Company received gross proceeds of approximately \$11.3 million, resulting in net proceeds of approximately \$10.1 million, from sales of its securities in registered offerings (see Note 7). During the third quarter, the Company received approximately \$144,000 from a federal grant.

The Company is focused primarily on the development and commercialization of innovative products in women's reproductive 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.

As of the date of this report and based on current business plan estimates, the Company believes it has sufficient cash to fund its operating expenses over at least the next twelve months from the date of issuance of these consolidated financial statements.

Although the Company has cash and cash equivalents of approximately \$9.5 million at September 30, 2018, the Company will need to raise additional capital through 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 Company cannot be sure that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company or its stockholders. 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, 2017, filed with the Securities and Exchange Commission, or SEC on March 28, 2018. Since the date of those 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, 2017.

#### ***Reverse Stock Split***

On July 20, 2017, the Company effected a 1-for-10 reverse stock split of its common stock. All share and per share amounts of common stock, options and warrants in these notes and those amounts included in the accompanying interim consolidated financial statements, have been restated for all periods to give retroactive effect to the reverse stock split.

### **Use of Estimates**

Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates include the fair value of stock-based compensation, goodwill impairment and purchase accounting. Actual results could differ from those estimates and could materially affect the reported amounts of assets, liabilities and future operating results.

### **Principles of Consolidation**

The interim consolidated financial statements of the Company are stated in U.S. dollars and are prepared using GAAP. These financial statements include the accounts of the Company and its wholly owned subsidiaries, Daré Bioscience Operations, Inc., Daré Bioscience Australia Pty LTD, and Pear Tree Pharmaceuticals, Inc. The financial statements of the Company's wholly owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in accumulated other comprehensive loss in the interim consolidated balance sheets. All significant intercompany transactions and accounts have been eliminated in consolidation.

### **Grant Funding**

The Company receives certain research and development funding through a grant issued by a division of the National Institutes of Health. The funding is recognized in the statement of operations as a reduction to research and development expense as the related costs are incurred to meet those obligations over the grant period. The Company adopted this policy in 2018. During the three and nine months ended September 30, 2018, the Company recognized approximately \$213,000 in the statement of operations as a reduction to research and development expense.

### **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 \$9.5 million and \$7.6 million measured at fair value as of September 30, 2018 and December 31, 2017, respectively, 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.

### **Recent Pronouncements Not Yet Adopted**

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. The Company is still in the process of evaluating the effect of adoption on its financial statements and expects to adopt the standard on January 1, 2019. The adoption is expected to lead to an increase in the assets and liabilities recorded on the Company's balance sheets due to the lease agreement attributable to leased office space.

### **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 August 2016, FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which intended to add or clarify guidance on the classification of certain cash receipts and payments on the statement of cash flows. The new guidance addresses cash flows related to: debt prepayment or extinguishment costs, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies and bank-owned life insurance policies, distributions received from equity method investees, beneficial interest in securitization transactions, and the application of predominance principle to separately identifiable cash flows. The standard became effective on January 1, 2018. The Company's adoption of this standard on January 1, 2018 did not have a material impact on the Company's interim consolidated financial statements.

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 January 2017, FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment (Topic 350)*. The guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. The guidance should be adopted on a prospective basis for the annual or any interim goodwill impairment tests beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company's adoption of this standard on September 30, 2017 did not have a material impact on the Company's consolidated financial statements.

In May 2017, FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*, which intended to provide clarity when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard became effective for the Company on January 1, 2018. The Company's adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In July 2017, FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): (I) Accounting for Certain Financial Instruments with Down Round Features, (II) Replacement for the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This update was issued to provide additional clarity related to accounting for certain financial instruments that have characteristics of both liabilities and equity. In particular, this update addresses freestanding and embedded financial instruments with down round features and whether they should be treated as a liability or equity instrument. Part II simply replaces the indefinite deferral for certain mandatorily redeemable non-controlling interests and mandatorily redeemable financial instruments of nonpublic entities contained within the ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company has early adopted ASU 2017-11. As a result, the Company has not recognized the fair value of the warrants containing down round features that were issued in the underwritten offering in February 2018 (see Note 7) as liabilities.

#### **4. ACQUISITIONS**

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

On July 19, 2017, the Company completed its business combination with Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, in accordance with the terms of the Stock Purchase Agreement dated as of March 19, 2017, or the Daré Stock Purchase Agreement, by and among the Company, Private Daré and the holders of capital stock and securities convertible into capital stock of Private Daré named therein, or the Private Daré Stockholders. Pursuant to the Daré Stock Purchase Agreement, each Private Daré Stockholder sold their shares of capital stock in Private Daré 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 because immediately upon completion of the transaction, Private Daré stockholders held a majority of the voting interest of the combined company. 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 is 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 unamortized fair value of such stock options relates to an option modification approved on March 19, 2017 that provided for an acceleration of vesting of such options upon a change in control event. Such modification became effective upon the closing of the Cerulean/Private Daré stock purchase transaction. Hence, the unamortized fair value of such stock options is deemed to be part of total purchase consideration and goodwill. Transaction costs associated with the Cerulean/Private Daré stock purchase transaction of \$0.96 million are included in general and administrative expense. The total purchase price consideration of approximately \$24.3 million represents the fair value of the shares of Cerulean stock issued in connection with the Cerulean/Private Daré stock purchase transaction and the unamortized fair value of the stock options described above, which was allocated as follows:

Purchase Consideration	(in thousands)	
Fair value of shares issued	\$	20,625
Unamortized fair value of Cerulean options		3,654
Fair value of total consideration	\$	<u>24,279</u>
Assets acquired and liabilities assumed		
Cash and cash equivalents	\$	9,918
Prepaid expense and other current assets		1,915
Accounts payable		(233)
Total assets acquired and liabilities assumed		<u>11,600</u>
Goodwill	\$	<u>12,679</u>

The final allocation of the purchase price depended on finalizing the valuation of the fair value of assets acquired and liabilities assumed. The Company retrospectively recorded purchase price adjustments at the acquisition date to increase current liabilities and current assets by \$23,609 and \$225,778, respectively, which reduced the original goodwill amount of \$12.9 million by \$202,169.

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 December 31, 2017. The Company determined there was an impairment and recognized an impairment charge of approximately \$7.5 million in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2017 and reduced the goodwill carrying value from approximately \$12.7 million to \$5.2 million on its consolidated balance sheet as of December 31, 2017.

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 are included in the Company's research and development expense.

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) will be offset against future payments otherwise due under the Merger Agreement to certain former and continuing Pear Tree service providers and former holders of Pear Tree's capital stock, or the Holders, including the potential \$75,000 payment due on the one-year anniversary of the closing of the merger. 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.

Under the Merger Agreement, the Holders will be eligible to receive, subject to certain offsets, tiered royalties, including customary provisions permitting royalty reductions and offset, based on percentages of annual net sales of certain products subject to license agreements the Company assumed and a percentage of sublicense revenue. The Company must also make contingent payments to the Holders that are based on achieving certain clinical, regulatory and commercial milestones, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock.

### **5. CONVERTIBLE PROMISSORY NOTES**

Prior to the Cerulean/Private Daré stock purchase transaction, Private Daré financed its operations through the sale of convertible promissory notes that entitled the holder to accrued interest at an annual rate of 8%. In the event of a preferred stock financing by Private Daré, all outstanding principal and unpaid interest under the convertible promissory notes would have converted into the shares of Private Daré's preferred stock issued in such financing at the price per share paid by the purchasers of such shares and an additional number of shares equal to, depending on the time of purchase, 20% to 40% of the outstanding principal and unpaid interest, or the conversion benefit. Private Daré issued a convertible promissory note in the principal amount of \$100,000 in February 2017 and issued additional convertible promissory notes in the aggregate principal amount of \$55,000 between April 1, 2017 and June 6, 2017.

In connection with the Cerulean/Private Daré stock purchase transaction, all outstanding convertible promissory notes were amended to provide that their principal amount plus accrued interest and taking into account their conversion benefit, would convert into shares of Private Daré common stock immediately prior to the closing of the Cerulean/Private Daré stock purchase transaction. The number of shares of Private Daré common stock issued upon conversion of the convertible promissory notes issued before March 31, 2017 was equal to (i) their outstanding principal amount plus accrued interest through March 31, 2017 multiplied by the respective conversion benefit, which ranged from 125% to 140%, divided by (ii) \$0.18727. The number of shares of Private Daré common stock issued upon conversion of the convertible promissory notes issued after March 31, 2017 was equal to (i) 120% of their outstanding principal amount, divided by (ii) \$0.38.

In connection with the closing of the Cerulean/Private Daré stock purchase transaction, all the outstanding shares of Private Daré common stock, including the shares issued upon conversion of the above described convertible promissory notes, were exchanged for shares of the Company's common stock at the exchange ratio specified in the Daré Stock Purchase Agreement.

The Company recognized interest expense of \$0 and \$316,804 at September 30, 2018 and September 30, 2017, respectively, relating to the convertible promissory notes.

## **6. STOCK-BASED COMPENSATION**

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

Prior to the Cerulean/Private Daré stock purchase transaction, the 2015 Employee, Director and Consultant Equity Incentive Plan of Private Daré, or the 2015 Private Daré Plan, governed the issuance of equity awards to Private Daré employees, officers, non-employee directors and consultants. Options granted under the 2015 Private Daré Plan have terms of ten years from the date of grant unless earlier terminated and generally vest over a three-year period. Upon closing of the Cerulean/Private Daré stock purchase transaction, the Company assumed the 2015 Private Daré Plan and each outstanding option to acquire Private Daré stock that was not exercised prior to the closing. Options to purchase 50,000 shares of Private Daré stock were assumed. Such options were assumed on the same terms as were applicable to them under the 2015 Private Daré Plan and became an option to purchase such number of shares of the Company's common stock equal to the number of Private Daré shares subject to such option multiplied by the exchange ratio specified in the Daré Stock Purchase Agreement, at a correspondingly adjusted exercise price. Based on the exchange ratio and after giving effect to the reverse stock split effected in connection with the closing of the Cerulean/Private Daré stock purchase transaction, such options were replaced with options to purchase 10,149 shares of the Company's common stock, all of which were outstanding as of September 30, 2018.

Private Daré issued 900,000 and 200,000 shares of fully vested restricted stock to non-employees under the 2015 Private Daré Plan during 2015 and 2016, respectively. In connection with the closing of the Cerulean/Private Daré stock purchase transaction, the Company assumed these shares and replaced them with 223,295 restricted shares of the Company's common stock (after giving effect to the reverse stock split effected in connection with the closing of the Cerulean/Private Daré stock purchase transaction).

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***

In March 2014, the Company's board of directors adopted, and its stockholders approved the 2014 Employee Stock Purchase Plan, or the ESPP, which became effective in April 2014. The ESPP permits eligible employees to enroll in a six-month offering period whereby participants may purchase shares of the Company's common stock, through payroll deductions, at a price equal to 85% of the closing price of the common stock on the first day of the offering period or on the last day of the offering period, whichever is lower. Purchase dates under the ESPP occur on or about June 30 and December 31 each year. The Company's board of directors decided not to initiate a new offering period beginning January 1, 2017 and no offering period has been initiated since then. There was no stock-based compensation related to the ESPP for the nine months ended September 30, 2018 or September 30, 2017.

### ***Amended and Restated 2014 Stock Incentive Plan***

The Company maintains the Amended and Restated 2014 Plan, or the Amended 2014 Plan, which was approved by the Company's stockholders on July 10, 2018. The Amended 2014 Plan was an amendment and restatement of the Company's 2014 Stock Incentive Plan, or the 2014 Plan.

The number of shares authorized for issuance under the Amended 2014 Plan is 2,046,885, which is the sum of (a) 1,509,463 shares of common stock plus (b) 537,422 shares of common stock subject to awards granted under the 2014 Plan. The number of authorized shares will increase 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.

In March 2017, the Company's board of directors approved two modifications to outstanding stock options granted under the 2014 Plan to participants providing services to the Company as of that date. One modification extended the exercise period of such stock options to two years after such participant's termination date, unless the exercise period absent such modification would be longer. The other modification provided for accelerated vesting of such stock options upon a change in control event. These modifications resulted in unamortized fair value expense of approximately \$3.7 million and was recorded as part of the total consideration in the Cerulean/Private Daré stock purchase transaction (see Note 4). The two modifications resulted in certain options remaining outstanding that would have otherwise expired.

At September 30, 2018, 451,244 shares of common stock were reserved for future issuance under the Amended 2014 Plan, and options to purchase 1,605,790 shares of the Company's common stock granted under the Amended 2014 Plan were outstanding.

### Summary of Stock Option Activity

The table below summarizes stock option activity under the Amended 2014 Plan, and related information for the nine months ended September 30, 2018. The exercise price of all options granted during the nine months ended September 30, 2018 was equal to the market value of the Company's common stock on the date of the grant. As of September 30, 2018, unamortized stock-based compensation expense of \$1,089,491 will be amortized over a weighted average period of 3.6 years.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2017 <sup>(1)</sup>	539,896	\$ 31.40
Granted	1,066,050	1.09
Exercised	—	—
Cancelled/expired	(156)	59.48
Outstanding at September 30, 2018 (unaudited)	<u>1,605,790</u>	<u>\$ 11.27</u>
Exercisable at September 30, 2018 (unaudited)	<u>535,031</u>	<u>\$ 31.62</u>

- (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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 5,494	\$ —	\$ 5,994	\$ —
General and administrative	34,497	6,947	52,544	6,953
Total	<u>\$ 39,991</u>	<u>\$ 6,947</u>	<u>\$ 58,538</u>	<u>\$ 6,953</u>

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the three and nine months ended September 30, 2018 are as follows:

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Expected life in years	10.0	10.0
Risk-free interest rate	2.90%	2.90%
Expected volatility	123%	123%
Forfeiture rate	0.0%	0.0%
Dividend yield	0.0%	0.0%
Weighted-average fair value of options granted	\$ 1.03	\$ 1.04

#### ***Restricted Stock After the Cerulean/Private Daré Stock Purchase Transaction***

The 3.14 million shares of common stock issued in connection with the Cerulean/Private Daré stock purchase transaction to the Private Daré stockholders were not registered with the SEC and may only be sold if registered under the Securities Act of 1933, as amended, or pursuant to an exemption from the registration requirements thereunder. The shares held by non-affiliates became eligible for sale under Rule 144 beginning six months after the closing of the Cerulean/Private Daré stock purchase transaction.

## **7. 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), including in sales made directly on the Nasdaq Capital Market, or Nasdaq, to or through a market maker or, subject to our prior approval, in negotiated transactions. The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement plus certain legal expenses. The common stock sales agreement was amended in August 2018 to refer to the Company's shelf registration statement on Form S-3 (File No. 333-227019) that was filed to replace the Company's shelf registration statement on Form S-3 (File No. 333-206396) that expired on August 28, 2018.

During the nine months ended September 30, 2018, the Company issued and sold 375,000 shares under the common stock sales agreement for gross proceeds of approximately \$1.0 million and incurred offering expenses of approximately \$336,000. All such shares were sold during January and 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 overallotment 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 overallotment option, and net proceeds of approximately \$9.4 million.

## Common Stock Warrants

The warrants issued in the February 2018 underwritten offering have an exercise price of \$3.00 per share and are exercisable immediately and for five years from issuance. 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 adjusted downward if the Company issues or sells (or is deemed to issue or sell) securities at a price that is less than the exercise price in effect immediately prior to such issuance or sale (or deemed issuance or sale). In that case, the exercise price of the warrants will be adjusted to equal the price at which the new securities are issued or sold (or are deemed to have been issued or sold). 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. The 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.

The Company has 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 and as a result has recorded the fair value of the warrants as equity (see Note 3).

No warrants were exercised during the nine months ended September 30, 2018 or 2017. During the nine months ended September 30, 2018, warrants to purchase 170 shares of the Company's common stock expired. As of September 30, 2018, the Company had these 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	\$	3.00	February 15, 2023
<u>3,750,833</u>			

## 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 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 12 issued patents worldwide and 8 patent applications, all of which are exclusively licensed to the Company for the human contraceptive use of Ovaprene under the terms of the ADVA-Tec Agreement. The license 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. The Company also has a right of first refusal to license these patents and patent applications for additional indications for Ovaprene.

The following is a summary of certain terms of the ADVA-Tec 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 must make payments of up to \$14.6 million in the aggregate to ADVA-Tec based on the achievement of specified development and regulatory milestones, which include the completion of a successful Postcoital Clinical Trial Study (as defined in the ADVA-Tec Agreement); approval by the FDA to commence the Phase 3 pivotal human clinical trial; successful completion of the Phase 3 pivotal human clinical trial; the FDA's acceptance of the filing of a PMA 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. The Company is also required to make up to \$20 million in the aggregate in commercial milestone payments to ADVA-Tec upon reaching certain worldwide net sales milestones. 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.

- **Royalty Payments.** After the commercial launch of Ovaprene, the Company is required to make royalty payments to ADVA-Tec based on aggregate annual net sales of Ovaprene in specified regions, which percentage royalty rate will vary between 1% and 10% and will increase based on various net sales thresholds.

- **Termination Rights.** The ADVA-Tec Agreement includes customary termination rights for both parties and provides the Company the right to terminate with or without cause in whole or on a country-by-country basis upon 60 days prior written notice. ADVA-Tec may terminate the agreement if the Company fails to do any of the following: (i) satisfy the annual spending obligation described above, (ii) use commercially reasonable efforts to complete all necessary pre-clinical and clinical studies required to support and submit a PMA, (iii) 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, where such failure is not caused by events outside of the Company's reasonable control, or (iv) 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, where non-enrollment is not caused by events outside of its reasonable control. In addition, ADVA-Tec may terminate the ADVA-Tec Agreement if the Company develops or commercializes any non-hormonal ring-based vaginal contraceptive device deemed competitive to Ovaprene or, in certain limited circumstances, if the Company fails to commercialize Ovaprene in certain designated countries within three years of the first commercial sale of Ovaprene.

### ***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. Under the SST License Agreement, the Company was required to secure an investment of at least \$10 million by March 31, 2018, which it did. 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 certain 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 tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.
- *Milestone Payments.* SST will be eligible to receive payments ranging from \$0.5 million to \$18.0 million on achieving certain clinical and regulatory milestones in the U.S. and worldwide, and an additional \$10.0 million to \$100 million upon achieving certain commercial 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.* Each party has customary rights to terminate the SST License Agreement in the event of material uncured breach by the other party. In addition: (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 one 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). The Company agreed to pay 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, 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. 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 up to \$43.8 million (up to \$13.5 million in clinical and regulatory milestones and up to \$30.3 million in 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 that 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).

### **Operating Lease**

The Company entered into a facility lease agreement that commenced on July 1, 2018 for 3,169 square feet of office space for its corporate headquarters. The term of the lease is 37 months and terminates on July 31, 2021. The Company has the option to extend the term of the lease for one year. The gross monthly base rent is \$8,873, which will increase approximately 4% per year, subject to certain future adjustments. The base rent was abated during the second month of the lease. Future minimum lease payments at September 30, 2018 total \$315,727. The Company recognizes rent expense by the straight-line method over the lease term. As of September 30, 2018, deferred rent totaled \$9,292.

## **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. The award will be applied to clinical development efforts supporting Oviparene. The balance of the award is contingent upon, among other matters, assessment of the results of the first phase of the research and availability of funds. The Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment. As of September 30, 2018, the Company has received payments totaling approximately \$144,000. The funding is recognized in the statement of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period. At September 30, 2018, the Company has recorded a receivable of approximately \$69,000 for expenses believed to be eligible for reimbursement incurred through September 30, 2018.

**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:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Stock options	1,605,790	545,640	1,605,790	545,640
Warrants	3,750,833	30,502	3,750,833	30,502
Total	<u>5,356,623</u>	<u>576,142</u>	<u>5,356,623</u>	<u>576,142</u>

## 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, 2017 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 28, 2018. 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 II, Item 1A of this report under the heading "Risk Factors," which are incorporated herein by reference.*

In this report: (a) "Cerulean" refers to Cerulean Pharma, Inc. before the Cerulean/Private Daré stock purchase transaction closed (as described in the "2017 Business Combination and Related Transactions" section below); and (b) "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 reproductive 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 such areas, 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 Private Daré, Daré Bioscience Australia Pty LTD, and Pear Tree Pharmaceuticals, Inc. operate in one business segment.

Since July of 2017, we have assembled a portfolio of clinical-stage and preclinical-stage candidates addressing unmet needs in women's reproductive health. We have used a variety of transaction structures to license, acquire, or obtain an option to acquire the rights to these assets.

Our two clinical-stage assets were obtained through product license and development agreements:

- Ovaprene, a non-hormonal monthly contraceptive candidate, was licensed in July of 2017 from ADVA-Tec, Inc.;
- Sildenafil Cream, 3.6%, a potential treatment for Female Sexual Arousal Disorder, or FSAD, was licensed in February of 2018 from Strategic Science & Technologies-D, LLC and Strategic Science & Technologies, LLC, or referred to collectively as SST.

Our preclinical candidates were obtained through these agreements:

- In March of 2018, we entered into a collaboration and option agreement with Orbis Biosciences Inc., or Orbis, covering new injectable contraceptive product candidates;

- in April of 2018, we licensed the worldwide rights to a portfolio of preclinical intravaginal rings from Juniper Pharmaceuticals, Inc., or Juniper;
- in May of 2018, we acquired Pear Tree Pharmaceuticals, Inc., or Pear Tree, a company that owns the rights to a proprietary vaginal tamoxifen tablet to treat vulvar and vaginal atrophy; and
- in July of 2018, we acquired certain assets from Hydra Biosciences, Inc., or Hydra, related to a novel target for non-hormonal contraceptives for both men and women.

We expect that the bulk of our development expenses over the next two years will support the advancement of our two clinical-stage product candidates, Ovaprene and Sildenafil Cream, 3.6%. We initiated a postcoital test, or PCT, clinical trial of Ovaprene in May of 2018, and we will commence Phase 2b related activities related to Sildenafil Cream, 3.6% during the fourth quarter of 2018. In addition to our clinical-stage programs, we also intend to fund a portion of the development expenses of our other preclinical stage assets. Any additional product candidates we may obtain in the future will also require cash to fund their development.

The Ovaprene intravaginal ring, if approved for marketing, requires no intervention at the time of intercourse, does not use hormones and would be intended to provide protection over multiple weeks of use. Ovaprene consists of a silicone-reinforced ring with a soft, absorbable scaffolding that encircles a fluid-permeable barrier. A non-braided, multi-filament mesh 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 that previously underwent a request for designation process within the Office of Combination Products at the U.S. Food and Drug Administration, or FDA. The FDA designated Center for Devices and Radiological Health, or CDRH, as the lead agency FDA program center for premarket review and product regulation; it also provided notice that CDRH has determined that a Premarket Approval, or PMA, will be required. We intend to develop Ovaprene based on PMA guidelines. If approved, Ovaprene would represent a new category of birth control. In a PCT pilot study conducted in 20 women and published in *The Journal of Reproductive Medicine*® in 2009, Ovaprene demonstrated the ability to immobilize sperm and prevent their progression into the cervical mucus.

The ongoing PCT clinical trial of Ovaprene is designed to assess general safety, acceptability, and effectiveness in preventing progressively motile sperm from reaching the cervical canal following intercourse. The study is enrolling 50 couples, with the woman to be evaluated over the course of five menstrual cycles, with a target of having at least 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 the Ovaprene non-hormonal vaginal ring (menstrual cycles 3, 4 and 5). Data from the PCT clinical trial is expected to be available in the second half of 2019. If Ovaprene demonstrates effectiveness in preventing most sperm from progressing into the cervical canal in the PCT clinical trial, 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.

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

We plan to pursue the 505(b)(2) regulatory pathway for Sildenafil Cream, 3.6% in the U.S. to leverage the existing data and established safety profile of the Viagra® brand. 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 it. Based on the FDA guidance we received from that

meeting, we will commence Phase 2b related activities during the fourth quarter of 2018 with the initiation of the content validity patient reported outcome, or PRO, study to demonstrate that the genital arousal symptoms we plan to assess in our Phase 2b and our pivotal studies are the most important and relevant to our target population and are also acceptable endpoints for the FDA. In parallel, we will continue to explore additional clinical and non-clinical work that might be valuable or required to support the overall program and the anticipated design of the Phase 2b. Because our plan is for the co-primary endpoints used in the Phase 2b to reflect the endpoints used in the Phase 3 trials, after the qualitative study is completed and before the Phase 2b at-home trial is initiated, we plan to request another Type C meeting to obtain the FDA's guidance on whether it agrees that the PRO instruments are content valid for the target population. The timing of when we initiate the Phase 2b at-home trial will be influenced by such guidance.

### **Financial Overview**

We incurred losses of approximately \$11.5 million for the year ended December 31, 2017. As of December 31, 2017, we had an accumulated deficit of approximately \$12.2 million and cash and cash equivalents of approximately \$7.6 million. We also had negative cash flow from operations of approximately \$2.5 million for the year ended December 31, 2017. As of September 30, 2018, we had (a) an accumulated deficit of approximately \$26.1 million and (b) cash and cash equivalents of approximately \$9.5 million. We also had negative cash flow from operations of approximately \$7.6 million during the nine months ended September 30, 2018.

### **2017 Business Combination and Related Transactions**

Until July 20, 2017, our corporate name was Cerulean Pharma Inc., or Cerulean. Cerulean was incorporated in Delaware in December 2005. On July 19, 2017, Cerulean and Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, completed a transaction in which the holders of capital stock and securities convertible into capital stock of Private Daré, which holders are collectively referred to as the Private Daré Stockholders, sold their shares of capital stock of Private Daré to Cerulean in exchange for newly issued shares of Cerulean common stock. As a result of that transaction, Private Daré became a wholly owned subsidiary of Cerulean. As of immediately following the closing of that transaction: (i) the Private Daré Stockholders owned approximately 51% of the outstanding common stock of Cerulean, and (ii) the equity holders of Cerulean immediately prior to the closing, collectively, owned approximately 49% of the outstanding common stock of Cerulean. In connection with the transaction, Cerulean changed its name from "Cerulean Pharma, Inc." to "Daré Bioscience, Inc." We refer to the transaction described above as the Cerulean/Private Daré stock purchase transaction.

On July 19, 2017, Cerulean also completed the sale of its proprietary Dynamic Tumor Targeting™ Platform to Novartis Institutes for BioMedical Research, Inc. for \$6.0 million.

On July 20, 2017, we effected a 1-for-10 reverse stock split of our common stock. All share and per share amounts of common stock, options and warrants in this report, including those amounts included in the accompanying interim consolidated financial statements, have been restated for all periods to give retroactive effect to the reverse stock split.

### **Financial Operations Overview**

The results of our operations discussed in this section (A) for the three and nine months ended September 30, 2018 and that include the period from July 19, 2017 to September 30, 2017 represent our operations after giving effect to the Cerulean/Private Daré stock purchase transaction, and (B) that include the period from January 1, 2017 to July 18, 2017 represent the operations of Private Daré, making a comparison between periods difficult.

### **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 or any combination of the foregoing. Any revenue generated is expected to fluctuate from quarter to quarter as a result of the timing and amounts of any such payments. 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 product candidates in a timely manner or to receive regulatory approval for such product candidates, our ability to generate future revenue and our results of operations would be materially adversely affected.

### **Research and Development Expenses**

Research and development expenses primarily represent costs incurred to conduct research and development of our product candidates. Also, included in research and development expenses are transaction costs related to the Pear Tree acquisition, which we acquired to secure the rights to develop a proprietary vaginal formulation of tamoxifen, DARE-VVA1, as a potential treatment for vulvar and vaginal atrophy. 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 Pear Tree acquisition; and
- internal costs 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 pre-clinical candidates—Ovaprene, Sildenafil Cream, 3.6%, 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, and 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. We expect to continue to incur additional expenses because of additional costs associated with being a public company, including expenses related to compliance with SEC and Nasdaq rules and regulations, additional insurance, investor relations, and other administrative expenses and professional services.

## 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 Annual Report on Form 10-K and Note 3 to our unaudited interim consolidated financial statements contained in this Quarterly Report on Form 10-Q.

## Results of Operations

### Comparison of Three Months Ended September 30, 2018 and 2017 (Unaudited)

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

	Three months ended September 30,		Change Dollars
	2018	2017	
Operating expenses:			
General and administrative expense	\$ 1,175,049	\$ 1,052,628	122,421
Research and development expenses	1,446,548	280,793	1,165,755
License expenses	—	—	—
Total operating expenses	<u>2,621,597</u>	<u>1,333,421</u>	1,288,176
Loss from operations	(2,621,597)	(1,333,421)	(1,288,176)
Other income (expense)	47,122	(296,262)	343,384
Net loss	<u>\$ (2,574,475)</u>	<u>\$ (1,629,683)</u>	(944,792)
Other comprehensive loss:			
Foreign currency translation adjustments	\$ (18,721)	\$ (9,774)	(8,947)
Comprehensive loss	<u>\$ (2,593,196)</u>	<u>\$ (1,639,457)</u>	(953,739)

## Revenues

We did not recognize any revenues for either of the three months ended September 30, 2018 or 2017.

### **General and administrative expenses**

The increase of \$122,421 in general and administrative expenses for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 was primarily attributable to increased personnel costs of approximately \$105,000 due to salary expense, including bonuses, due to increased headcount in the current period, increased travel expense of approximately \$41,000 related to business development activities in the current period, and increased insurance costs of approximately \$34,000 related to directors and officers insurance policies and employee benefits. Following the Cerulean/Private Daré stock purchase transaction and based upon the recommendation of our compensation consultant and approval of the Compensation Committee of our Board of Directors, we began paying our newly appointed executive officers compensation at a level in line with market rates for executive officers of early stage, pre-commercial biopharmaceutical public companies.

### **Research and development expenses**

The increase of \$1.17 million in research and development expenses for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 was primarily attributable to approximately \$956,000 of increased development costs associated with our lead product candidates, Ovaprene and Sildenafil Cream, 3.6%, offset by grant funding received and recorded as a reduction to research and development expense of approximately \$213,000, approximately \$121,000 of increased spending on our pre-clinical product candidates, \$55,000 of costs associated with our acquisition of certain assets from Hydra, a \$75,000 payment to Orbis made under the terms of the Orbis Agreement to conduct first stage development work, and approximately \$185,000 of increased payroll and related expense due to increased headcount in the current period.

### **License expenses**

There were no license expenses for either of the three months ended September 30, 2018 or September 30, 2017.

### **Other income (expense)**

The increase of \$343,384 in other income (expense) for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 was primarily due to interest expense associated with convertible notes of \$316,804 at September 30, 2017 with no comparable expense in the current period. For further discussion, see Note 5, "Convertible Promissory Notes" of the Notes to the Interim Consolidated Financial Statements (Unaudited).

### **Comparison of Nine Months Ended September 30, 2018 and 2017 (Unaudited)**

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

	<u>Nine months ended September 30,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>Dollars</u>
Operating expenses:			
General and administrative	\$ 3,635,413	\$ 1,729,338	1,906,075
Research and development expenses	4,750,823	312,169	4,438,654
License expenses	350,000	—	350,000
Impairment of goodwill	5,187,519	—	5,187,519
Total operating expenses	<u>13,923,755</u>	<u>2,041,507</u>	11,882,248
Loss from operations	(13,923,755)	(2,041,507)	(11,882,248)
Other income (expense)	101,492	(330,233)	431,725
Net loss	<u>\$ (13,822,263)</u>	<u>\$ (2,371,740)</u>	(11,450,523)
Other comprehensive loss:			
Foreign currency translation adjustments	\$ (59,952)	\$ (9,774)	(50,178)
Comprehensive loss	<u>\$ (13,882,215)</u>	<u>\$ (2,381,514)</u>	(11,500,701)

## **Revenues**

We did not recognize any revenue for either of the nine months ended September 30, 2018 or 2017.

## **General and administrative expenses**

The increase of \$1.91 million in general and administrative expenses for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 was primarily attributable to an increase in personnel costs of approximately \$747,000 due to increased salary expense, including bonuses, due to increased headcount in the current period, an increase in legal and professional services of approximately \$610,000 related to being a public company, completing two financings and multiple product acquisition transactions, an increase in insurance costs of approximately \$255,000 related to directors and officers insurance policies and employee benefits, an increase in rent expense of approximately \$73,000 due to a full nine months of rent expense in the current period versus two months of rent expense in the same period of the prior year, and an increase in travel expense of approximately \$86,000 due to expanded business development efforts in the current period. Following the Cerulean/Private Daré stock purchase transaction and based upon the recommendation of our compensation consultant and approval of the Compensation Committee of our Board of Directors, we began paying our newly appointed executive officers compensation at a level in line with market rates for executive officers of early stage, pre-commercial biopharmaceutical public companies.

## **Research and development expenses**

The increase of \$4.44 million in research and development expenses for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 was primarily attributable to approximately \$3.1 million of increased development costs associated with our lead product candidates, Oviprene and Sildenafil Cream, 3.6%, offset by grant funding received and recorded as a reduction to research and development expense of approximately \$213,000, approximately \$519,000 of increased payroll and related expense, approximately \$452,000 of transaction costs associated with our acquisition of Pear Tree, approximately \$127,000 of increased development costs associated with our pre-clinical product candidates, \$225,000 in payments to Orbis made under the terms of the Orbis Agreement to conduct first stage development work, and \$55,000 of costs associated with our acquisition of certain assets from Hydra.

## **License expenses**

The increase of \$350,000 in license expenses for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 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, see Note 8, "Commitments and Contingencies" of the Notes to the Interim Consolidated Financial Statements (Unaudited).

## **Goodwill impairment expense**

We incurred an impairment loss of \$5.2 million for the nine months ended September 30, 2018 due to our determination that the carrying amount of our goodwill exceeded its estimated fair value at March 31, 2018. See Note 4, "Acquisitions," of the Notes to the Interim Consolidated Financial Statements (Unaudited) appearing in this report for a discussion of our goodwill analysis.

## **Other income (expense)**

The increase of \$431,725 in other income (expense) for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 was primarily due to interest expense associated with convertible notes of \$316,804 at September 30, 2017 with no comparable expense in the current period. For further discussion, see Note 5, "Convertible Promissory Notes" of the Notes to the Interim Consolidated Financial Statements (Unaudited).

## Liquidity and capital resources

We have a history of losses from operations and anticipate that we will continue to incur losses for at least the next several years. For the nine months ended September 30, 2018, we incurred a net loss from operations of \$13.8 million. At September 30, 2018, our accumulated deficit was approximately \$26.1 million, we had cash and cash equivalents of approximately \$9.5 million and working capital of approximately \$9 million. We also had negative cash flow from operations of approximately \$7.6 million during the nine months ended September 30, 2018.

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, milestone payments due upon the successful advancement of our product candidates, legal expenses, other regulatory expenses and general overhead costs.

We expect our expenses to increase in connection with the PCT clinical trial of Oviprene, clinical and other studies related to Sildenafil Cream, 3.6%, efforts to advance other portfolio candidates, and any other development activities we may undertake in the future. We also expect to continue to incur additional costs given the requirements of operating as a public company.

We have not generated any revenue to date, and we cannot anticipate if, and when we will generate any revenue. 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, we believe our existing cash balances will be sufficient to satisfy our working capital needs and other liquidity requirements associated with our planned operations for at least the next 12 months.

We will require additional capital to continue to fund our operations and to successfully execute our current operating plan, including the development of our current product portfolio, and we are currently evaluating a variety of financing options, including financings, government or other grant funding, collaborations and strategic alliances.

## Cash Flows

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

	Nine months ended September 30,	
	2018	2017
Net cash used in operating activities	\$ (7,558,047)	\$ (1,579,060)
Net cash provided by (used in) investing activities	(518,836)	9,918,440
Net cash provided by financing activities	10,114,452	155,000
Effect of exchange rate changes on cash and cash equivalents	(59,952)	(9,774)
Net increase in cash	<u>\$ 1,977,617</u>	<u>\$ 8,484,606</u>

## Net cash used in operating activities

Cash used in operating activities for the nine months ended September 30, 2018 included the net loss of \$13.8 million, decreased by non-cash impairment of goodwill of \$5.2 million, acquired in-process research and development expense of approximately \$507,000, and non-cash stock-based compensation expense of \$58,538. Components providing operating cash in this period were a \$236,259 increase of accounts payable and accrued expenses, a \$203,928 decrease in other receivables, a \$105,692 decrease in other non-current assets and deferred charges, and a \$193,495 decrease in other current assets. A component reducing operating cash in this period was a \$238,378 increase in prepaid expenses.

Cash used in operating activities for the nine months ended September 30, 2017 included the net loss of \$2.4 million, decreased by noncash charges of \$6,953 and non-cash interest of \$316,804. A component reducing operating cash in this period was a \$227,233 increase of prepaid expenses and other current assets, offset by a \$659,223 increase in accounts payable and accrued expenses.

***Net cash provided by (used in) investing activities***

Cash used in investing activities for the nine months ended September 30, 2018 consisted of approximately \$452,000 of transaction costs associated with our acquisition of Pear Tree, \$55,000 of costs associated with our acquisition of certain assets from Hydra, and \$11,836 related to the purchase of property and equipment.

Cash provided by investing activities for the nine months ended September 30, 2017 was approximately \$9.9 million, consisting of cash acquired through the Cerulean/Private Daré stock purchase transaction.

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

Cash provided by financing activities for the nine months ended September 30, 2018 consisted of \$10.1 million of proceeds from the underwritten public offering completed in February 2018 and sales under the common stock sales agreement completed in January and February 2018.

Cash provided by financing activities for the nine months ended September 30, 2017 was \$155,000, consisting of proceeds from issuing convertible promissory notes.

***License and Royalty Agreements***

We may have to make various royalty and milestone payments under the product license and development agreements related to our two clinical-stage assets, Ovaprene and Sildenafil Cream, 3.6%, and under the other agreements related to our preclinical candidates. For further discussion of these potential payments, see Note 8, "Commitments and Contingencies," of the Notes to the Interim Consolidated Financial Statements (Unaudited).

***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 September 30, 2018 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 quarter ended September 30, 2018 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 Annual Report on Form 10-K for the year ended December 31, 2017, or our 2017 10-K, in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, or our 2018 Q1 10Q, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, or our 2018 Q2 10Q, in addition to other information in this report, including the information below and our financial statements and related notes thereto, 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 2017 10-K, in Part II, Item 1A. Risk Factors in our 2018 Q1 10-Q, and in Part II Item 1A. Risk Factors in our 2018 Q2 10Q, except as described below.

#### **Risks Related to Our Business**

***We have incurred significant losses since our inception and expect to incur continued losses due to the active expansion of our portfolio of product candidates. We must raise additional funds to finance our operations and remain a going concern.***

Since inception, we have incurred significant operating losses. We incurred a net loss of approximately \$13.8 million for the nine months ended September 30, 2018. At September 30, 2018, our accumulated deficit was approximately \$26.1 million. Negative cash flows from our operations are expected to continue for the foreseeable future. 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. Such losses may fluctuate, the fluctuations may be substantial, and we may never become profitable.

Our capital needs have been and will continue to be highly dependent on the product development programs we choose to pursue, particularly our programs for Oviprene and Sildenafil Cream, 3.6%, the progress of these programs, the results of our preclinical studies and clinical trials, the cost, timing and outcomes of regulatory decisions regarding a potential approval for any one or more of our current or future product candidates we may choose to develop, the terms of our contracts with service providers and license partners, and the rate of recruitment of patients in our clinical trials. In addition, the continuation of our clinical trials, and possibly our entire business, will depend on results of upcoming analyses and our financial resources at that time. Should our product development efforts succeed, we will need to develop a commercialization plan for each product developed, which would also require significant resources to develop and implement.

We will need to raise additional capital through financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to successfully execute our current operating plan and to continue the development of our current product candidates. 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 we will be able to raise capital when needed or on terms favorable to us and our 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 or cease operations, any of which would have a negative impact on our financial condition. See also “—Our ability to raise capital may be limited by applicable laws and regulations.”

***Our ability to raise capital may be limited by applicable laws and regulations.***

In January and February 2018, we raised approximately \$11.3 million in gross proceeds through the sale of our equity securities under a Form S-3 “shelf” registration statement. Using a shelf registration statement to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. We currently have a Form S-3 shelf registration statement effective. However, our ability to raise capital under that registration statement may be limited by, among other things, current SEC rules and regulations. Under current SEC rules and regulations, we must meet certain requirements to use our Form S-3 registration statement to raise capital without restriction as to the amount of the market value of securities sold thereunder. One such requirement is that we periodically evaluate the market value of our outstanding shares of common stock held by non-affiliates, or public float, and if, at an evaluation date, our public float is less than \$75.0 million, then the aggregate market value of securities sold by us or on our behalf under the Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. Our public float is currently approximately \$9.8 million and therefore we are currently subject to the one-third of our public float limitation. Assuming our public float remains the same amount the next time we are required to evaluate it, we will only be able to sell up to approximately \$3.3 million using our Form S-3 shelf registration statement. If our ability to use our Form S-3 shelf registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act of 1933 or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to using our Form S-3 shelf registration statement.

In addition, under current SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to use a Form S-3 registration statement (i) for a primary offering, if our public float is not at least \$75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). While currently our common stock is listed on the Nasdaq Capital Market, there can be no assurance that we will be able to maintain such listing.

Our ability to timely raise sufficient additional capital also may be limited by Nasdaq’s stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock in an offering other than a public offering (as defined in Nasdaq listing rules). For instance, generally, stockholder approval is required prior to the issuance or potential issuance of common stock (or securities convertible into or exercisable for common stock) which (together with sales by our officers, directors and substantial shareholders (as defined in Nasdaq listing rules)) equals 20% or more of our common stock outstanding before the issuance at a price that is less than the lower of the closing price of our common stock or the five trading day average closing price of our common stock, in each case, immediately preceding the signing of the binding agreement (the “Minimum Price”). A public offering under Nasdaq rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the company’s stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if we were able to raise capital through other means. In addition, certain prior sales of our securities by us may be aggregated with an offering we may propose in the future, further limiting the amount we could raise in any future offering that is not considered a public offering by Nasdaq and involves the sale, issuance or potential issuance by us of our common stock (or securities convertible into or exercisable for common stock) at a price that is less than the Minimum Price. Under Nasdaq listing rules, stockholder approval is also required prior to the issuance of securities when the issuance or potential issuance will result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our business plan, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

**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		
4.1	<a href="#">Form of Amendment to Warrant to Purchase Common Stock entered into as of June 27, 2018</a>					X
10.1	<a href="#">Amendment No. 1 to Common Stock Sales Agreement, dated August 24, 2018, between Daré Bioscience, Inc. and H.C. Wainwright &amp; Co., LLC</a>	8-K	001-36395	08/27/18	10.2	
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>					X
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>					X
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: November 13, 2018

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

Date: November 13, 2018

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

## AMENDMENT TO WARRANT TO PURCHASE COMMON STOCK

This Amendment to Warrant to Purchase Common Stock (this "Amendment") is entered into as of June 27, 2018, between Daré Bioscience, Inc., a Delaware corporation (the "Company"), and the undersigned warrant holder ("Holder").

**WHEREAS**, the Company issued to Holder a Warrant to Purchase Common Stock on February 15, 2018 (the "Warrant").

**WHEREAS**, the Company and Holder desire to amend the Warrant to clarify the definition of "Excluded Securities" as set forth herein.

**NOW, THEREFORE**, for good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged and agreed, the parties hereby agree to amend the Warrant, effective as of the date the Warrant issued, as follows:

1. Amendment to Definition of Excluded Securities. The definition of Excluded Securities set forth in Section 17(q) of the Warrant is hereby deleted in its entirety and replaced with:

"(q) '**Excluded Securities**' means (i) shares of Common Stock or standard options to purchase Common Stock issued to directors, officers or employees of the Company for services rendered to the Company in their capacity as such pursuant to an Approved Stock Plan (as defined above), provided that (A) during the six (6) month period following the Subscription Date, all such issuances (taking into account the shares of Common Stock issuable upon exercise of such options) after the Subscription Date pursuant to this clause (i) do not, in the aggregate, exceed more than 5% of the Common Stock issued and outstanding immediately prior to the Subscription Date, and (B) the exercise price of any such options is not lowered, none of such options are amended to increase the number of shares issuable thereunder and none of the terms or conditions of any such options are otherwise materially changed in any manner that adversely affects any of the Buyers; (ii) shares of Common Stock issued upon the conversion or exercise of Convertible Securities (other than standard options to purchase Common Stock issued pursuant to an Approved Stock Plan that are covered by clause (i) above) issued prior to the Subscription Date, provided that the conversion price of any such Convertible Securities (other than standard options to purchase Common Stock issued pursuant to an Approved Stock Plan that are covered by clause (i) above) is not lowered, none of such Convertible Securities (other than standard options to purchase Common Stock issued pursuant to an Approved Stock Plan that are covered by clause (i) above) are amended to increase the number of shares issuable thereunder and none of the terms or conditions of any such Convertible Securities (other than standard options to purchase Common Stock issued pursuant to an Approved Stock Plan that are covered by clause (i) above) are otherwise materially changed in any manner that adversely affects any of the Buyers; and (iii) the shares of Common Stock issuable upon exercise of the Registered Warrants; provided, that the terms of the Registered Warrant are not amended, modified or changed on or after the Issuance Date (other than antidilution adjustments pursuant to the terms thereof in effect as of the Issuance Date)."

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2. Miscellaneous. Except as specifically provided in this Amendment, no other amendments, revisions or changes are made to the Warrant. All other terms and conditions of the Warrant remain in full force and effect. This Amendment may be attached to and shall form a part of the Warrant. This Amendment may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Delivery of an executed counterpart of a signature page to this Amendment by facsimile or in electronic (i.e., "pdf" or "tif") format shall be effective as delivery of a manually executed counterpart of this Amendment. This Amendment shall be governed by, and construed and interpreted in accordance with, the laws of the State of New York, without regard to principles of conflicts of law. This Amendment will be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, personal representatives, successors and permitted assigns.

*[Signature Pages Follow.]*

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**IN WITNESS WHEREOF**, the parties hereto have executed this **AMENDMENT** as of the date first set forth above.

**COMPANY:**  
Daré Bioscience, Inc.

By:  
Name:  
Title:

**HOLDER** (if an entity):  
  
(Printed Name)

By:  
Name:  
Title:

**HOLDER** (if an individual):

Signature:  
Name:

## CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

Date: November 13, 2018

/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: November 13, 2018

/s/ Lisa Walters-Hoffert  
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Lisa Walters-Hoffert

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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 September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

Date: November 13, 2018

/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 September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

Date: November 13, 2018

/s/ Lisa Walters-Hoffert

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Lisa Walters-Hoffert

Chief Financial Officer

(principal financial officer)