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

(Mark One)

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

For the quarterly period ended March 31, 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)

Delaware
(State or Other Jurisdiction
of Incorporation)

Commission File No. 001-36395

20-4139823
(IRS Employer
Identification No.)

11119 North Torrey Pines Road, Suite 200
La Jolla, CA
(Address of Principal Executive Offices)

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

92037
(Zip Code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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"/> (Do not check if a smaller reporting company)	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 May 7, 2018 a total of 11,422,161 shares of the Registrant's Common Stock, par value \$0.0001, were issued and outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, in particular "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," of Part I. Financial Information, and the information incorporated by reference herein contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements include all statements that are not historical facts and, 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 if needed, 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 the FDA's Section 505(b)(2);*
 - 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 agreement covering the critical patents and related intellectual property related to our product candidate;*
 - 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;*
 - 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;*
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- *Lack of precedent to help assess whether health insurance plans will cover one of 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;*
- *A limitation of our market opportunity caused by the lack of patent protection for the active ingredients in certain of our product candidates and other formulations and delivery technology and systems that may be developed by competitors;*
- *Higher risk of failure associated with product candidates in preclinical stages of development, which may not be valued by investors and may be 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 overall stock markets, 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.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2018 (unaudited)	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	\$ 15,625,026	\$ 7,559,846
Other receivables	28,888	284,206
Prepaid expenses	290,877	311,571
Other current assets	—	193,495
Total current assets	<u>15,944,791</u>	<u>8,349,118</u>
Goodwill	—	5,187,519
Other non-current assets	686,060	723,191
Total assets	<u>\$ 16,630,851</u>	<u>\$ 14,259,828</u>
Liabilities and Stockholders' equity		
Current Liabilities		
Accounts payable and accrued expenses	\$ 807,607	\$ 966,653
Total current liabilities	<u>807,607</u>	<u>966,653</u>
Deferred rent	2,888	392
Total liabilities	<u>810,495</u>	<u>967,045</u>
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 March 31, 2018 and December 31, 2017, respectively	1,142	605
Accumulated other comprehensive loss	(31,826)	(18,080)
Additional paid-in capital	35,747,609	25,541,210
Accumulated deficit	(19,896,569)	(12,230,952)
Total stockholders' equity	<u>15,820,356</u>	<u>13,292,783</u>
Total liabilities and stockholders' equity	<u>\$ 16,630,851</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)

	Three months ended March 31,	
	2018	2017
Operating expenses:		
General and administrative	\$ 1,303,189	\$ 200,663
Research and development expenses	1,086,653	27,800
License expenses	100,000	—
Impairment of goodwill	5,187,519	—
Total operating expenses	<u>7,677,361</u>	<u>228,463</u>
Loss from operations	(7,677,361)	(228,463)
Other income (expense)	11,744	(15,400)
Net loss	<u>\$ (7,665,617)</u>	<u>\$ (243,863)</u>
Foreign currency translation adjustments	<u>\$ (13,746)</u>	<u>\$ —</u>
Comprehensive loss	<u>\$ (7,679,363)</u>	<u>\$ (243,863)</u>
Loss per common share - basic and diluted	<u>\$ (0.88)</u>	<u>\$ (0.27)</u>
Weighted average number of common shares outstanding:		
Basic	<u>8,684,550</u>	<u>910,000</u>

See accompanying notes to interim consolidated financial statements.

The operations presented in the interim consolidated financial statements and accompanying notes for the three months ended March 31, 2018 represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and for the three months ended March 31, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 1, "Organization of the Business," 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)

	Three months ended March 31,	
	2018	2017
Operating activities:		
Net loss	\$ (7,665,617)	\$ (243,863)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,124	3
Impairment of goodwill	5,187,519	—
Changes in operating assets and liabilities, net impact of acquisition:		
Other receivables	255,318	—
Prepaid expenses	20,694	—
Other current assets	193,495	(2,800)
Other assets and deferred charges	37,131	—
Accounts payable and accrued expenses	(159,047)	180,660
Interest payable	—	15,405
Deferred rent	2,496	—
Net cash used in operating activities	<u>(2,118,887)</u>	<u>(50,595)</u>
Financing activities:		
Net proceeds from issuance of common stock and warrants	10,197,813	—
Proceeds from issuance of convertible promissory notes	—	100,000
Net cash provided by financing activities	<u>10,197,813</u>	<u>100,000</u>
Effect of exchange rate changes on cash and cash equivalents	(13,746)	—
Net change in cash and cash equivalents	8,065,180	49,405
Cash and cash equivalents, beginning of period	7,559,846	44,614
Cash and cash equivalents, end of period	<u>\$ 15,625,026</u>	<u>\$ 94,019</u>

See accompanying notes to interim consolidated financial statements.

The operations presented in the interim consolidated financial statements and accompanying notes for the three months ended March 31, 2018 represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and for the three months ended March 31, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 1, "Organization of the Business," 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., a Delaware corporation, was formed on November 28, 2005. Daré Bioscience, Inc. and its wholly owned subsidiaries, Daré Bioscience Operations, Inc. and Daré Bioscience Australia Pty LTD, operate in one segment. The term the “Company” as used herein refers collectively to Daré Bioscience, Inc. and its wholly owned subsidiaries, unless otherwise stated or the context otherwise requires.

The Company is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women’s reproductive health. 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 primarily in the areas of contraception, vaginal health, sexual health and fertility, some of which have existing clinical proof-of-concept data, and to take those candidates through advanced stages of clinical development.

Over the last twelve months, the Company has assembled a portfolio of two clinical-stage assets through product license and development agreements. The first, Ovaprene®, is a non-hormonal monthly contraceptive candidate that was licensed in July of 2017; and the second, Topical Sildenafil cream, also known as SST-6007, is a potential treatment for Female Sexual Arousal Disorder and was licensed in February of 2018. In addition, if the merger contemplated by the agreement and plan of merger the Company entered into with Pear Tree Pharmaceuticals, Inc. and certain other parties in April of 2018 is consummated, the Company will acquire a third clinical-stage asset—a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. During the same period, the Company obtained rights to a portfolio of preclinical candidates. In March of 2018, the Company entered into a collaboration and option agreement covering a new injectable contraceptive product candidate, and in April of 2018, the Company licensed the worldwide rights to a portfolio of preclinical intravaginal rings from Juniper Pharmaceuticals, Inc.

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 shareholders of the Company. That transaction is referred to as the Cerulean/Private Daré stock purchase transaction. In accordance with the terms of the Daré Stock Purchase Agreement, the Company changed its name from “Cerulean Pharma Inc.” to “Daré Bioscience, Inc.” References in this Quarterly Report on Form 10-Q to “Cerulean” refer to Cerulean Pharma Inc. prior to the closing of the Cerulean/Private Daré stock purchase transaction.

The operations presented in the accompanying interim consolidated financial statements and in these notes for the three months ended March 31, 2018 represent the operations of the Company after giving effect to the Cerulean/Private Daré stock purchase transaction. The interim consolidated financial statements and accompanying notes for all periods prior to the Cerulean/Private Daré stock purchase transaction represent the operations of Private Daré, making a comparison between periods difficult.

The Company’s operations have consisted primarily of raising capital, product research and development, and initial market development.

The Company has not generated any revenue related to its primary business purpose to date and is subject to a number of risks common to other clinical-stage biopharmaceutical companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of product candidates. The Company is also subject to a number of risks similar 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 three months ended March 31, 2018, the Company incurred a net loss of \$7.7 million. At March 31, 2018, the Company had an accumulated deficit of approximately \$19.9 million and had cash and cash equivalents of approximately \$15.6 million. The Company also had negative cash flow from operations of approximately \$2.1 million during the three months ended March 31, 2018.

On January 4, 2018, the Company entered into an at-the-market issuance common stock sales agreement, under which the Company may sell stock from time to time up to an aggregate of \$10.0 million in gross proceeds. During the three months ended March 31, 2018, the Company generated gross proceeds of approximately \$1.1 million, resulting in net proceeds of approximately \$835,000 on sales of 375,000 shares of common stock under this agreement. In February 2018, the Company also generated gross proceeds of approximately \$10.3 million, resulting in net proceeds of \$9.4 million from an underwritten offering of 5.0 million shares of common stock and warrants to purchase up to 3.5 million shares of common stock. All of the financing transactions completed during the first quarter of 2018 were registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-206396), or the Registration Statement, and the related base prospectus included in the Registration Statement, as supplemented by the prospectus supplements dated January 4, 2018 and February 14, 2018.

The Company will need additional capital over time to further fund the development of, and seek regulatory approvals for, its current product candidates and any future candidates it may license as well as to commercialize any approved products. If additional funding is not available on a timely basis or at adequate levels, the Company will need to reevaluate its operating plans. The interim consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company is currently focused primarily on the development and commercialization of innovative products in women's reproductive health and believes such activities will result in the Company's continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of the Company's product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if the Company's product candidates, if approved, fail to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash and cash equivalents on hand and through a combination of equity offerings, debt financings, government or other grant funding, collaborations and strategic alliances. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders.

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. In the event the Company acquires, licenses or develops any new products or product candidates that have not been contemplated in the current business plan, the amount required to fund future operations could increase, possibly materially. In order to acquire or develop additional products and product candidates, the Company will require additional capital over time.

The Company expects that its net losses will continue for at least the next several years as it seeks to acquire, license or develop additional products and product candidates. Such losses may fluctuate, the fluctuations may be substantial, and the Company may never become profitable.

3. 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.

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

The preparation of 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., and Daré Bioscience Australia Pty LTD. 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.

Recent Accounting Pronouncements Not Yet Adopted

On May 28, 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. As the Company does not currently have any contracts with customers, it does not experience any impact from this accounting standard.

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 currently assessing the potential impact of this accounting standard and the effect it might have on the financial statements.

Recently Adopted Accounting Standards

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 the following: 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.

Fair Value Measurements

U.S. generally accepted accounting principles define 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 \$15.6 million and \$7.6 million measured at fair value as of March 31, 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.

4. Acquisitions

As further discussed in Note 1, on July 19, 2017, the Cerulean/Private Daré stock purchase 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 that were granted by Cerulean and outstanding prior to the closing of the transaction 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 \$24.28 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 that were granted by Cerulean and outstanding prior to the closing of the transaction that were assumed on July 19, 2017 in connection with the closing of the transaction, 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	\$	24,279
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		11,600
Goodwill	\$	12,679

The final allocation of the purchase price was dependent on the finalization of the valuation of the fair value of assets acquired and liabilities assumed and may have differed from the amounts included in the interim consolidated financial statements. The Company retrospectively recorded purchase price adjustments at the acquisition date to increase current liabilities by \$23,609 and increase current assets by \$225,778, resulting in a \$202,169 reduction to the original goodwill amount of approximately \$12.9 million.

The Company tests its goodwill for impairment 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 tested 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, 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. Further, it reduced the carrying value of goodwill 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 that 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.

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% and were convertible into Private Daré's next preferred stock financing round. In the event of a preferred stock financing, 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 between April 1, 2017 and June 6, 2017, Private Daré issued additional convertible promissory notes in the aggregate principal amount of \$55,000.

In connection with the Cerulean/Private Daré stock purchase transaction, all outstanding convertible promissory notes were amended such that the principal amount of each note plus accrued interest thereon, and taking into account the conversion benefit of such note, would convert into shares of common stock of Private Daré immediately prior to consummation of the stock purchase transaction. The number of shares of Private Daré common stock issued upon conversion of the convertible promissory notes for notes issued prior to March 31, 2017 was equal to (i) the 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 for notes issued after March 31, 2017 was equal to (i) 120% of the outstanding principal amount, divided by (ii) \$0.38.

Immediately prior to the closing of the Cerulean/Private Daré stock purchase transaction, all the outstanding convertible promissory notes were converted into shares of common stock of Private Daré, and in connection with such closing, all of the outstanding shares of common stock of Private Daré were exchanged for shares of common stock of the Company at the exchange ratio specified in the Daré Stock Purchase Agreement.

The Company recognized an expense of \$0 and \$15,405 at March 31, 2018 and March 31, 2017, respectively, relating to outstanding convertible debt.

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 Plan, governed the issuance of incentive stock options, non-qualified stock options, stock grants and other stock-based awards to individuals who were then employees, officers, non-employee directors or consultants of Private Daré. Options granted under the 2015 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 2015 Plan was assumed by the Company and each outstanding option to acquire stock of Private Daré that was not exercised prior to such closing was assumed on the same terms and conditions as were applicable under the 2015 Plan, and became an option to acquire such number of shares of the Company's common stock as was equal to the number of Private Daré shares subject to such unexercised option multiplied by the exchange ratio specified in the Daré Stock Purchase Agreement, at a correspondingly adjusted exercise price. There were outstanding unexercised options to purchase 50,000 shares of Private Daré stock that were assumed in connection with the closing of the Cerulean/Private Daré stock purchase transaction, and which, 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 were replaced with options to purchase 10,149 shares of the Company's common stock, all of which were outstanding as of March 31, 2018.

Private Daré issued 900,000 and 200,000 shares of fully vested restricted stock to non-employees under the 2015 Plan during the years ended December 31, 2016 and December 31, 2015, respectively. On July 19, 2017, these shares were assumed by the Company and were replaced 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), all of which were outstanding as of March 31, 2018.

There were no options or restricted stock granted under the 2015 Plan during the three months ended March 31, 2017 and effective as of July 19, 2017 following the closing of the Cerulean/Private Daré stock purchase transaction, no further awards may be granted under the 2015 Plan.

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 board of directors decided against initiating a new offering period beginning January 1, 2017. There was no stock-based compensation related to the ESPP for the three months ended March 31, 2018 or March 31, 2017.

2014 Stock Incentive Plan

Options granted under the Company's 2014 Stock Incentive Plan, or the 2014 Plan, have terms of no more than ten years from the date of grant unless earlier terminated. A total of 240,000 shares of common stock were initially reserved for issuance under the 2014 Plan. In addition, "returning shares" that may become available from time to time are added back to the plan. "Returning shares" are shares that are subject to outstanding awards granted under the 2014 Plan that expire or terminate prior to exercise or settlement, are forfeited because of failure to vest, are repurchased, or are withheld to satisfy tax withholding or purchase price obligations in connection with such awards. At March 31, 2018, 142,979 shares of common stock were reserved for future issuance under the 2014 Plan.

The Company's board of directors approved two modifications to the stock options issued under the 2014 Plan to participants who were providing services to the Company as of March 19, 2017. The Company extended the exercise period for such stock options to two years beyond such participant's termination date, unless the original option terms provided for a longer exercise period, and provided for the acceleration of vesting for such stock options upon a change in control event. Modifications to the existing option terms 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 and discussed in Note 4.

As of March 31, 2018, there were stock options outstanding to purchase up to 533,247 shares of the Company's common stock that were granted under the 2014 Plan.

A summary of stock option activity with regard to the 2015 Plan and the 2014 Plan, and related information for the three months ended March 31, 2018 is set forth in the table below. The exercise price of all options granted during the three months ended March 31, 2018 and 2017 was equal to the market value of the Company's common stock on the date of the grant. As of March 31, 2018, \$40,103 represents unamortized stock-based compensation expense which will be amortized over the weighted average period of 2.13 years.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2017 ⁽¹⁾	539,896	\$ 31.40
Granted	3,500	2.37
Exercised	—	—
Cancelled/expired	—	—
Outstanding at March 31, 2018 (unaudited)	<u>543,396</u>	<u>\$ 31.21</u>
Exercisable at March 31, 2018 (unaudited)	<u>526,338</u>	<u>\$ 32.10</u>

- (1) Includes 10,149 shares subject to options granted by Private Daré that were assumed in connection with the Cerulean/Private Daré stock purchase transaction.

Compensation Expense

The Company has recorded stock-based compensation expense related to the issuance of stock option awards to employees of \$9,124 and \$3 for the three months ended March 31, 2018 and March 31, 2017, respectively.

There were no stock options granted during the three months ended March 31, 2017. The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the three months ended March 31, 2018 are as follows:

	Three months ended March 31, 2018
Expected life in years	10.0
Risk-free interest rate	2.52%
Expected volatility	122%
Forfeiture rate	0.0%
Dividend yield	0.0%
Weighted-average fair value of options granted	\$ 2.26

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 shareholders of Private Daré have not been 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 SEC's registration requirements. These shares held by non-affiliates became eligible for sale pursuant to Rule 144 beginning six months after the closing date of the Cerulean/Private Daré stock purchase transaction.

7. Stockholders' Equity

At-The-Market Issuance Sales Agreement

On January 4, 2018, the Company entered into an at-the-market issuance common stock sales agreement pursuant to 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.

During the three months ended March 31, 2018, the Company generated gross proceeds of approximately \$1.1 million and incurred issuance costs of \$237,403 under this agreement on sales of an aggregate of 375,000 shares of the Company's common stock.

Underwritten Public Offering

On February 15, 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 together with a warrant to purchase up to 0.70 of a share of the Company's common stock, at an exercise price of \$3.00 per share. The offering, including shares issued upon exercise of the underwriter's overallotment option, generated gross proceeds of \$10.3 million, and after the payment of expenses, the Company received net proceeds of approximately \$9.4 million. The warrants are exercisable immediately and for a period of five years from the date of issuance. The warrants include a price-based anti-dilution provision, which provides that 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), before the expiration of the warrant term. In that case, the new exercise price of the warrants would 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 holders of the warrants shall 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 the registration statement of which the prospectus registering the offering was part is not effective for the issuance of the shares underlying the warrants, in which case the warrants

may be exercised on a cashless basis. The Company granted the underwriters a 30-day option to purchase up to an additional 750,000 shares of its common stock and warrants to purchase up to 525,000 shares of its common stock directly from the Company at a price of \$2.05 per common share and accompanying warrant. The Company received an overallotment notice from the underwriter for warrants to purchase up to 220,500 shares of its common stock, which were issued on February 15, 2018.

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. As described above at Note 3, Recently Adopted Accounting Standards, the Company early adopted ASU 2017-11 and as a result has recorded the fair value of the warrants as equity.

Common Stock Warrants

No warrants were exercised during the three months ended March 31, 2018 or 2017. As of March 31, 2018, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
169	\$ 17.70	August 8, 2018
2,906	\$ 12.04	December 1, 2021
3,737	\$ 12.04	December 6, 2021
17,190	\$ 6.05	January 8, 2020
6,500	\$ 1.00	April 4, 2026
3,720,500	\$ 3.00	February 15, 2023
3,751,002		

8. Commitments and Contingencies

License and Research Agreements

ADVA-Tec License Agreement

On March 19, 2017, the Company entered into a license agreement, or the ADVA-Tec Agreement, with ADVA-Tec, Inc., or ADVA-Tec, under which it was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. The ADVA-Tec Agreement became effective once the Company secured the initial funding required in accordance with its terms. 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 these interim consolidated financial statements, this patent portfolio includes 12 issued patents worldwide, along with 8 patent applications, all of which in accordance with the terms of the ADVA-Tec Agreement are exclusively licensed to the Company for the human contraceptive use of Ovaprene. The Company also has a right of first refusal to license these patents and patent applications for purposes of additional indications for Ovaprene. Under the ADVA-Tec Agreement, 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.

Under the ADVA-Tec Agreement, the Company is required to 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. In addition, after the commercial launch of Ovaprene, the Company is also 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.

Finally, 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.

The Company is obligated to 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.

The license the Company received under the ADVA-Tec Agreement continues on a country-by-country basis until the later of the life of the licensed patents or the Company's last commercial sale of Ovaprene. 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. In addition, ADVA-Tec may terminate the ADVA-Tec 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 that is 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.

For products currently in development, future potential milestone payments based on product development are approximately \$14.6 million as of March 31, 2018. Future potential milestone payments related to commercialization totaled \$20 million at March 31, 2018. There are royalties ranging from 1-10% required under the ADVA-Tec Agreement. The Company is unable to estimate with certainty the timing of when these milestone payments will occur, as these payments are dependent upon the progress of the Company's product development programs.

SST License and Collaboration Agreement

On February 11, 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, pursuant to which the Company was required to secure an investment of at least \$10.0 million by March 31, 2018. The Company announced that it had met this funding requirement on February 15, 2018. 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 citrate 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.

Under the terms of the SST License Agreement, 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 fifty percent (50%) undivided interest in all joint inventions. Each party has agreed to collaborate through a Joint Development Committee, or JDC, which shall be responsible for determining the strategic objectives for, and generally overseeing, the development efforts of both parties under the SST License Agreement. Further, the Company has agreed to use commercially reasonable efforts to develop the Licensed Products in the Field of Use in accordance with a development plan contained in the SST License Agreement, and to commercialize the Licensed Products in the Field of Use.

The SST License Agreement provides that, in consideration of the rights to be granted to the Company, 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, including customary provisions permitting royalty reductions and offset, and a percentage of sublicense revenue. The Company is also responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it is required to perform under the SST

License Agreement. Further, the SST License Agreement provides that the Company shall make milestone payments to SST 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. Should the Company enter into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST.

The Company's license received under the SST License Agreement continues on a country-by-country basis until the later of ten 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. The SST License Agreement provides that each party will have customary rights to terminate the SST License Agreement in the event of material uncured breach by the other party, and, (i) 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 will have the right to terminate the SST License Agreement without cause upon ninety (90) days prior written notice to SST, and (ii) following receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA Approval, the Company will have a right to terminate the SST License Agreement without cause upon one hundred eighty (180) days prior written notice. In addition, the SST License Agreement provides SST with the right to terminate the SST License Agreement with respect to the applicable Licensed Product(s) in the applicable country(ies) upon thirty (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 sixty (60) days of receipt of SST's notice thereof.

Upon expiration (but not termination) of the SST License Agreement in a particular country, the Company shall 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.

Orbis Development and Option Agreement

On March 12, 2018, the Company entered into an exclusive development and option agreement with Orbis Biosciences, or Orbis, for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). The Company has agreed to pay Orbis \$300,000 to conduct the first stage of development work, Stage One, as follows: \$150,000 upon signing the Development and Option Agreement, \$75,000 at the fifty percent (50%) completion point, not later than six (6) months following signing of Development and Option Agreement, and \$75,000 upon delivery by Orbis of the 6-month batch, not later than eleven (11) months following signing of Development and Option Agreement. Upon Orbis successfully completing Stage 1 of the development program and achieving the predetermined target milestones for Stage 1, the Company will have ninety (90) days to instruct Orbis in writing whether or not to commence the second stage of development work, Stage 2. Should the Company execute its option to proceed to Stage 2, it will be obligated to provide additional funding to Orbis for such activities.

The initial development on Orbis's long-acting injectable contraceptive program was carried out under a subcontract funded by Family Health International, through a grant from the Bill and Melinda Gates Foundation.

An injectable contraceptive is designed to provide discreet, non-implanted, protection over several months. Limitations of the currently marketed injectable contraceptive is that it provides contraceptive protection for only three months and can delay the ability to get pregnant for up to ten months after receiving the injection. The target product profiles of ORB-204 and ORB-214 include prolonged duration (six to 12 months), improved ease of use, with an improved side effect profile and predictable return to fertility.

Pre-clinical studies for the 6- and 12-month formulations have been completed to date, 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 terms of the agreement with Orbis provide the Company with an option to enter into a license agreement for ORB-204 and ORB-214 should upcoming development efforts be successful.

9. Net Loss Per Share

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under outstanding options and warrants to purchase shares of the Company's common stock. Common share equivalents are excluded from the diluted net loss per share calculation if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted net loss per common share for the period indicated because of their anti-dilutive effect:

	Three months ended March 31,	
	2018	2017
Stock options	543,396	10,149
Warrants	3,751,002	—
Total	<u>4,294,398</u>	<u>10,149</u>

10. Subsequent Events

Juniper Pharmaceuticals - License Agreement

On April 24, 2018, the Company entered into an Exclusive License Agreement, or the Juniper License Agreement, with Juniper Pharmaceuticals, Inc., or Juniper, pursuant to 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 the material 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 is required to make potential future development and sales milestone payments of up to \$43.75 million (up to \$13.50 million in development milestones and up to \$30.25 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 is required to 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.

Funding Award from the National Institutes of Health

On April 30, 2018, the Company announced that it 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 important clinical development efforts supporting the Company's lead product candidate Ovaprene. 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.

Pear Tree Pharmaceuticals Acquisition

On April 30, 2018, the Company entered into an Agreement and Plan of Merger, or the Merger Agreement, with Pear Tree Pharmaceuticals, Inc., or Pear Tree, Daré Merger Sub, Inc., the Company's wholly-owned subsidiary, or Merger Sub, and Fred Mermelstein and Stephen C. Rocamboli, in their respective capacities as stockholders' representatives. If the transactions contemplated by the Merger Agreement are consummated, then at such time Merger Sub will merge with and into Pear Tree with Pear Tree surviving the merger as a wholly owned subsidiary of the Company.

Upon the potential closing of the Merger Agreement, certain former and continuing Pear Tree service providers and former holders of Pear Tree's capital stock, or the Holders, will be entitled to receive an amount of cash equal to the sum of \$75,000, and the cash and cash equivalents held by Pear Tree at closing, or the Positive Consideration Amount, less (i) certain indebtedness and transaction expenses of Pear Tree, (ii) transaction expenses of the stockholders' representatives and (iii) amounts payable under Pear Tree's management incentive plan, collectively referred to as the Negative Consideration Amount. In accordance with the Merger Agreement, if the Negative Consideration Amount is greater than the Positive Consideration Amount, then the Company will be allowed to offset such difference from future payments that would otherwise be due to the Holders, including the potential payment of \$75,000 due on the one-year anniversary of the closing. The Merger Agreement also provides that 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 assumed by the Company, and a percentage of sublicense revenue. Further, the Merger Agreement provides that the Company shall make milestone payments to the Holders, with such payments contingent on achieving certain clinical, regulatory and commercial milestones, which payments may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock, as more fully set forth in the Merger Agreement. The parties have made customary representations, warranties, and covenants in the Merger Agreement, including provisions regarding indemnification.

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.

References in this Quarterly Report on Form 10-Q: (a) to "Cerulean" refer to Cerulean Pharma, Inc. prior to the closing of the Cerulean/Private Daré stock purchase transaction (as described in the "2017 Business Combination and Related Transactions" section below); and (b) to "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.

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.

Over the last twelve months, we have assembled a portfolio of two clinical-stage assets through product license and development agreements. The first, Ovaprene, is a non-hormonal monthly contraceptive candidate that was licensed in July of 2017; and the second, Topical Sildenafil cream, also known as SST-6007, is a potential treatment for Female Sexual Arousal Disorder and was licensed in February of 2018. During the same period, we obtained rights to a portfolio of preclinical candidates. In March of 2018, we entered into a collaboration and option agreement covering new injectable contraceptive product candidates, and in April 2018, we licensed the worldwide rights to a portfolio of preclinical intravaginal rings from Juniper Pharmaceuticals, Inc. In addition, if the merger contemplated by the merger agreement entered into between us and with Pear Tree Pharmaceuticals, Inc. in April of 2018 are consummated, or the Pear Tree Merger, then we will acquire a third clinical-stage asset—a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy.

Since 2015, we have devoted significant resources to license and prepare for the development of Ovaprene, a non-hormonal contraceptive intravaginal ring intended to provide protection over multiple weeks of use, requiring no intervention at the time of intercourse. We acquired the worldwide rights to SST-6007, a potential treatment for FSAD, in February 2018. We expect that the bulk of our development expenses over the next two years will support the advancement of these two product candidates. However, we recently obtained rights to certain preclinical stage assets and, if the Pear Tree Merger is consummated, will obtain rights to an additional clinical stage asset that will require us to spend cash resources to fund their development. Any additional product candidates we may obtain in the future will also require funding.

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 \$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 March 31, 2018, we had an accumulated deficit of approximately \$19.9 million and cash and cash equivalents of approximately \$15.6 million as of March 31, 2018. We also had negative cash flow from operations of approximately \$2.1 million during the three months ended March 31, 2018. As further discussed below, in at-the-market offerings and in an underwritten public offering that we closed in early 2018, we received net proceeds of approximately \$10.4 million in the aggregate. We will need to raise substantial additional capital to continue to fund our operations. The amount and timing of future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. If we do not raise capital as and when needed, we will not be able to continue development of our product candidates or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations.

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.

We and our wholly owned subsidiaries, Private Daré and Daré Bioscience Australia Pty LTD, operate in one business segment.

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

Recent Events

Capital Raising

On January 4, 2018, we entered into an at-the-market issuance of common stock sales agreement pursuant to which we may sell up to an aggregate of \$10 million worth of shares of our common stock from time to time in “at-the-market” offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended), including in sales made directly on Nasdaq, to or through a market maker or, subject to our prior approval, in negotiated transactions. We will pay an aggregate commission rate of up to 3% of the gross proceeds of any common stock sold under this agreement. In January and February 2018, we generated gross proceeds of approximately \$1.1 million resulting in net proceeds of an aggregate of approximately \$840,000 on sales of 375,000 shares of our common stock under this agreement.

On February 15, 2018, we closed an underwritten public offering of 5.0 million shares of our common stock and warrants to purchase up to 3.5 million shares of common stock. Each share of common stock was sold together with a warrant to purchase up to 0.70 of a share of common stock, at an exercise price of \$3.00 per share. We generated gross proceeds of approximately \$10.3 million, resulting in net proceeds of approximately \$9.4 million. The warrants are exercisable immediately and for a period of five years from the date of issuance. The warrants include a price-

based anti-dilution provision, which provides that the exercise price of the warrants will be adjusted downward if we issue or sell (or are 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), before the expiration of the warrant term. In that case, the new exercise price of the warrants would equal the price at which the new securities are issued or sold (or are deemed to have been issued or sold). In addition, if we issue, sell or enter into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of our common stock, the holders of the warrants shall 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 the registration statement of which the prospectus registering the offering was part is not effective for the issuance of the shares underlying the warrants, in which case the warrants may be exercised on a cashless basis. We granted the underwriters a 30-day option to purchase up to an additional 750,000 shares of our common stock and warrants to purchase up to 525,000 shares of our common stock directly from us at a price of \$2.05 per common share and accompanying warrant. We received an overallotment notice from the underwriter for warrants to purchase up to 220,500 shares of our common stock, which shares were issued on February 15, 2018.

SST-6007 License and Collaboration Agreement

On February 11, 2018, we entered into a license and collaboration agreement, or the SST License Agreement, with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC, or referred to collectively as SST. Under the SST License Agreement, subject to our securing an investment of at least \$10.0 million by March 31, 2018, which we secured as a result of the underwritten public offering that closed on February 15, 2018 discussed above, we obtained a worldwide 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 citrate 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 SST Licensed Products.

We agreed to use commercially reasonable efforts to develop the SST Licensed Products in the SST Field of Use in accordance with a development plan contained in the SST License Agreement, and to commercialize the SST Licensed Products in the SST Field of Use.

SST will be eligible to receive tiered royalties based on percentages of annual net sales of the SST Licensed Products in the single digits to the mid-double digits, including customary provisions permitting royalty reductions and offset, and a percentage of sublicense revenue. We are responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it is required to perform under the SST License Agreement. Further, the SST License Agreement provides that we shall make base milestone payments to SST 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. Should we enter into strategic development or distribution partnerships related to the SST Licensed Products, additional milestone payments would be due to SST.

Orbis Development and Option Agreement

On March 12, 2018 we entered into an exclusive development and option agreement with Orbis Biosciences, or Orbis, for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). The collaboration represents our first partnership that leverages funds and development work supported to date by investment from a donor and non-profit development community devoted to improving options in women's reproductive health, positioning us as a committed industry partner to advance innovation that addresses global gaps in therapeutic options. We have agreed to pay Orbis \$300,000 to conduct the first stage of development work, Stage One, as follows: \$150,000 upon signing the Development and Option Agreement, \$75,000 at the fifty percent (50%) completion point, not later than six (6) months following signing of Development and Option Agreement, and \$75,000 upon delivery by Orbis of the 6-month batch, not later than eleven (11) months following signing of Development and Option Agreement. Upon Orbis successfully completing Stage 1 of the development program and achieving the predetermined target milestones for Stage 1, the Company will have ninety (90) days to instruct Orbis in writing whether or not to

commence the second stage of development work, Stage 2. Should we execute our option to proceed to Stage 2, we will be obligated to provide additional funding to Orbis for such activities.

The initial development on Orbis's long-acting injectable contraceptive program was carried out under a subcontract funded by Family Health International, or FHI 360, through a grant from the Bill and Melinda Gates Foundation, or the Gates Foundation. The Gates Foundation and FHI 360 are world leaders in the funding and development of novel contraceptive products and programs. In July of 2017, the Gates Foundation announced a commitment of \$375 million over three years in support of Family Planning 2020, a global public/private partnership aimed at providing access to contraception.

An injectable contraceptive is designed to provide discreet, non-implanted protection over several months. Limitations of the currently marketed injectable contraceptive is that it provides contraceptive protection for only three months and can delay the ability to get pregnant for up to ten months after receiving the injection. The target product profiles of ORB-204 and ORB-214 include prolonged duration (six to 12 months), improved ease of use, with an improved side effect profile and predictable return to fertility.

Pre-clinical studies for the 6- and 12-month formulations have been completed to date, 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 terms of the agreement with Orbis provide us with an option to enter into a license agreement for ORB-204 and ORB-214 should upcoming development efforts be successful.

Juniper Exclusive License Agreement

On April 24, 2018, we entered into an Exclusive License Agreement, or the Juniper License Agreement, with Juniper Pharmaceuticals, Inc., or Juniper, pursuant to which Juniper granted Daré (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. Daré is entitled to sublicense the rights granted to it under the Juniper License Agreement.

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

- *Upfront Fee.* We paid a \$250,000 non-creditable upfront license fee to Juniper in connection with the execution of the Juniper License Agreement.
- *Annual Maintenance Fee.* We 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.* We are required to make potential future development and sales milestone payments of up to \$43.75 million (up to \$13.50 million in development milestones and up to \$30.25 in sales milestones) for each product or process covered by the licenses granted under the Juniper License Agreement.
- *Royalty Payments.* During the royalty term, we 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, we will pay Juniper a low double-digit percentage of all sublicense income that we receive 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.* We are required to 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 earlier 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 Daré's uncured breach of any payment obligation under the Juniper License Agreement, (2) if we fail to maintain required insurance, (3) immediately upon our insolvency or the making of an assignment for the benefit of our creditors or if a bankruptcy petition is filed for or against us, which petition is not dismissed within 90 days, or (4) upon 60 days' notice for any uncured material breach by us of any of our other obligations under the Juniper License Agreement. We 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 we terminate 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 us.

Pear Tree Pharmaceuticals Acquisition

On April 30, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Pear Tree Pharmaceuticals, Inc., or Pear Tree, Daré Merger Sub, Inc., our wholly-owned subsidiary, or Merger Sub, and Fred Mermelstein and Stephen C. Rocamboli, in their respective capacities as stockholders' representatives. If the Pear Tree Merger is consummated, then at such time Merger Sub will merge with and into Pear Tree with Pear Tree surviving the merger as our wholly owned subsidiary.

Upon the potential closing of the Pear Tree Merger, certain former and continuing Pear Tree service providers and former holders of Pear Tree's capital stock, or the Holders, will be entitled to receive an amount of cash equal to the sum of \$75,000, and the cash and cash equivalents held by Pear Tree at closing, or the Positive Consideration Amount, less (i) certain indebtedness and transaction expenses of Pear Tree, (ii) transaction expenses of the stockholders' representatives and (iii) amounts payable under Pear Tree's management incentive plan, collectively referred to as the Negative Consideration Amount. In accordance with the Merger Agreement, if the Negative Consideration Amount is greater than the Positive Consideration Amount, then we will be allowed to offset such difference from future payments that would otherwise be due to the Holders, including the potential payment of \$75,000 due on the one-year anniversary of the closing. The Merger Agreement also provides that 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 assumed by Daré, and a percentage of sublicense revenue. Further, the Merger Agreement provides that we shall make milestone payments to the Holders, with such payments contingent on achieving certain clinical, regulatory and commercial milestones, which payments may be paid, in our sole discretion, in cash or in shares of our common stock, as more fully set forth in the Merger Agreement. The parties have made customary representations, warranties, and covenants in the Merger Agreement, including provisions regarding indemnification.

Financial Operations Overview

The results of our operations discussed in this section and the operations presented in the interim consolidated financial statements and accompanying notes for the three months ended March 31, 2018 represent our operations after giving effect to the Cerulean/Private Daré stock purchase transaction. The interim consolidated financial statements and accompanying notes for the three months ended March 31, 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 a combination of 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. 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, the receipt of regulatory approvals to market such products and the eventual successful commercialization of product candidates. If we fail to complete the development of product candidates in a timely manner or to obtain 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 represent costs incurred to conduct research and development of our product candidates. We recognize all research and development expenses as they are incurred. Research and development expenses consist primarily of the following:

- 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; and
- internal costs that are associated with activities performed by our research and development organization and generally benefit multiple programs.

We expect research and development expenses to increase in the future as Ovaprene, SST-6007, vaginal tamoxifen, if acquired, and any other potential product candidates that we may choose to develop are advanced into and through clinical trials in the pursuit of regulatory approvals. Such activities will require a significant increase in investment in regulatory support, clinical supplies, inventory build-up related costs and the payment of success-based milestones. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to, among other factors, license fee and/or milestone payments.

The process of 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 are unable to 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. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, Daré evaluates these estimates and judgments. We base our estimates on historical experience and on various assumptions that Daré believes 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. Daré believes that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Results of Operations — Comparison of Three Months Ended March 31, 2018 and 2017

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

	Three months ended March 31,		Change Dollars
	2018	2017	
Operating expenses:			
General and administrative expense	\$ 1,303,189	\$ 200,663	1,102,526
Research and development expenses	1,086,653	27,800	1,058,853
License expense	100,000	—	100,000
Impairment of goodwill	5,187,519	—	5,187,519
Total operating expenses	7,677,361	228,463	7,448,898
Loss from operations	(7,677,361)	(228,463)	(7,448,898)
Other income (expense)	11,744	(15,400)	27,144
Net Loss	<u>\$ (7,665,617)</u>	<u>\$ (243,863)</u>	(7,421,754)
Other comprehensive loss:			
Foreign currency translation adjustments	\$ (13,746)	\$ —	(13,746)
Comprehensive loss	<u>\$ (7,679,363)</u>	<u>\$ (243,863)</u>	(7,435,500)

Revenues

We did not recognize any revenue for the three months ended March 31, 2018 or 2017.

General and administrative expenses

The increase of \$1,102,526 in general and administrative expenses for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017 was primarily attributable to an increase in legal and professional services of \$568,133 related to the costs of being a public company, an increase in personnel costs of \$250,166 due to salary expense in the current period, including bonuses, with no comparable expense in the same period of the prior year, an increase in insurance costs of \$128,412 related to directors and officers insurance policies and employee benefits, with no comparable expense in the prior period, and an increase in taxes and licenses of \$42,122 with no comparable expense in the prior 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 \$1,058,853 in research and development expenses for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017 was entirely related to an increase in Ovaprene development costs in the current period.

Goodwill impairment expense

We incurred an impairment loss of \$5,187,519 for the three months ended March 31, 2018 due to our determination that the carrying amount of our goodwill exceeded its estimated fair value at March 31, 2018. See Note 4, "Acquisition," of the Notes to the Interim Consolidated Financial Statements (Unaudited) appearing in this report for a discussion of our goodwill analysis.

License expense

The increase of \$100,000 in license expense for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017 was entirely related to fees paid to Strategic Science and Technologies-D, LLC and Strategic Science Technologies, LLC, referred to collectively as SST. For further discussion, see Note 8, Commitments and Contingencies of the Notes to the Interim Consolidated Financial Statements (Unaudited).

Other income (expense)

The increase of \$27,144 in other income (expense) for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017 was primarily due to dividends earned on cash balances in the current period.

Liquidity and Capital Resources

We have a history of annual losses from operations and we anticipate that we will continue to incur losses for at least the next several years. As of March 31, 2018, we had incurred a net loss from operations of \$7.7 million, our accumulated deficit was \$19.9 million, we had \$15.6 million in cash and cash equivalents and we had working capital of \$15.1 million.

We have not generated any revenue to date, and we cannot anticipate if, and when we will generate any revenue. Future product revenue will require us to obtain regulatory approvals in order to sell any products. Revenue from potential strategic partnerships will also require us to advance clinical candidates to meaningful development milestones. At the same time, we expect our expenses to increase in connection with the postcoital clinical study of Ovaprene 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.

Our primary uses of capital are, and we expect will continue to be, staff-related expenses, clinical trial costs, contract manufacturing services, third-party clinical research and development services, legal and other regulatory expenses and general overhead costs.

We believe our existing cash balances, including the \$10.2 million of net proceeds we received from financings completed during the first quarter ended March 31, 2018, 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.

Based on our current plans and existing cash balances, we believe that our available funds will be sufficient for us to commence and complete a postcoital clinical trial of Ovaprene during 2018 and to advance SST-6007 into a Phase 2b clinical trial. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our available cash resources sooner than we currently expect.

We will continue to require additional capital to continue to fund our operations to successfully execute our current operating plan, to continue the development of our current product candidates, including a pivotal contraceptive study, to expand our product portfolio, to support new licenses or other rights related to future portfolio candidates, and if successful, to commercialize any approved products. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of clinical development efforts.

We intend to cover our future operating expenses through cash and cash equivalents on hand and through a combination of equity offerings, debt financings, government or other grant funding, collaborations and strategic alliances. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our current stockholders will be diluted. There can be no assurance that we will be able to raise additional capital when needed. If we are unable to raise additional capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations, any of which would have a negative impact on our financial condition.

Cash Flows

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

	Three months ended March 31,	
	2018	2017
Net cash used in operating activities	\$ (2,118,887)	\$ (50,595)
Net cash provided by financing activities	10,197,813	100,000
Effect of exchange rate changes on cash and cash equivalents	(13,746)	—
Net increase in cash	<u>\$ 8,065,180</u>	<u>\$ 49,405</u>

Net cash used in operating activities

Cash used in operating activities for the three months ended March 31, 2018 included the net loss of \$7,665,617, decreased by non-cash impairment of goodwill of \$5,187,519, and non-cash stock-based compensation expense of \$9,124. A major component reducing operating cash in this period was a \$159,046 decrease of accounts payable and accrued expenses. Major components providing operating cash were a \$255,318 decrease in other receivables and a \$193,495 decrease in other current assets.

Cash used in operating activities for the three months ended March 31, 2017 included the net loss of \$243,863. A major component reducing operating cash in this period was a \$2,800 increase in other current assets. Major components providing operating cash included a \$180,660 increase in accounts payable and accrued expenses.

Net cash provided by financing activities

Cash provided by financing activities for the three months ended March 31, 2018 consisted of proceeds from the underwritten public offering completed in February 2018 and sales under the at-the-market offering agreement completed in January and February 2018.

Cash provided by financing activities for the three months ended March 31, 2017 consisted of proceeds from the issuance of convertible promissory notes.

License and Royalty Agreements

SST-6007

On February 11, 2018, we entered into the SST License Agreement with SST, pursuant to which we were required to secure an investment of at least \$10 million by March 31, 2018. We announced that we had met this funding requirement on February 15, 2018. The SST License Agreement provides us with an exclusive, royalty-bearing, sublicensable license to develop and commercialize the SST Licensed Products in the SST Field of Use.

Under the terms of the SST License Agreement, we retain rights to inventions made by our employees, SST retains rights to inventions made by its employees, and each party shall own a fifty percent (50%) undivided interest in all joint inventions. Each party has agreed to collaborate through a Joint Development Committee, or JDC, which shall be responsible for determining the strategic objectives for, and generally overseeing, the development efforts of both parties under the SST License Agreement. Further, we have agreed to use commercially reasonable efforts to develop the SST Licensed Products in the SST Field of Use in accordance with a development plan contained in the SST License Agreement, and to commercialize the SST Licensed Products in the SST Field of Use.

The SST License Agreement provides that, in consideration of the rights to be granted to us, SST will be eligible to receive tiered royalties based on percentages of annual net sales of SST Licensed Products in the single digits to the mid double digits, including customary provisions permitting royalty reductions and offset, and a percentage of sublicense revenue. We are also responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it is required to perform under the SST License Agreement. Further, the SST License Agreement provides that we shall make milestone payments to SST ranging from \$0.5 million to \$18 million on achieving certain clinical and regulatory milestones in the U.S. and worldwide, and an additional \$10 million to \$100 million upon achieving certain commercial milestones. Should we enter into strategic development or distribution partnerships related to the SST Licensed Products, additional milestone payments would be due to SST.

Our license received under the SST License Agreement continues on a country-by-country basis until the later of ten years from the date of the first commercial sale of such SST Licensed Product or the expiration of the last valid claim of patent rights covering the SST Licensed Product in the SST Field of Use. The SST License Agreement provides that each party will have customary rights to terminate the SST License Agreement in the event of material uncured breach by the other party, and, (i) prior to receipt of approval by a regulatory authority necessary for commercialization of a SST Licensed Product in the corresponding jurisdiction, including New Drug Application Approval, or NDA Approval, we will have the right to terminate the SST License Agreement without cause upon ninety (90) days prior written notice to SST, and (ii) following receipt of approval by a regulatory authority necessary for commercialization of a SST Licensed Product in the corresponding jurisdiction, including NDA Approval, we will have a right to terminate the SST License Agreement without cause upon one hundred eighty (180) days prior written notice. In addition, the SST License Agreement provides SST with the right to terminate the SST License Agreement with respect to the applicable SST Licensed Product(s) in the applicable country(ies) upon thirty (30) days' notice to us if we fail to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan and do not cure such failure within sixty (60) days of receipt of SST's notice thereof.

Upon expiration (but not termination) of the SST License Agreement in a particular country, we shall have a fully paid-up license under the licensed intellectual property to develop and commercialize the applicable SST Licensed Products in the applicable country on a non-exclusive basis.

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 therefore Daré believes that our non-cancelable obligations under these agreements are not 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 March 31, 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 March 31, 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

There have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017 other than as described below.

Risks Related to Our Business

We have incurred significant losses since our inception and expect to incur continued losses in the future 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 \$7.7 million for the quarter ended March 31, 2018. At March 31, 2018, our accumulated deficit was approximately \$19.9 million. Negative cash flows from our operations are expected to continue for the foreseeable future. Based on our current operating plan, our current cash reserves are sufficient to fund operations for at least 12 months.

Our utilization of cash has been and will continue to be highly dependent on the product development programs we choose to pursue, particularly our programs for Ovaprene and Topical Sildenafil (also known as SST-6007), 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 our current product candidates or any future product candidates we may choose to develop, the terms and conditions 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 quite possibly our entire business, will depend on results of upcoming analyses and our financial resources at the time. Should our product development efforts be successful, we will need to develop a commercialization plan for each product developed, which would also require significant resources.

We will need to raise additional capital through public or private equity financings, debt financings, strategic partnerships or other types of arrangements in order to successfully execute our current operating plan and to continue the development of our current product candidates. See also “—We expect to be heavily reliant on our ability to raise capital through capital market transactions. Due to our small public float, low market capitalization, limited operating history and lack of revenue, it may be difficult and expensive for us to raise additional funds.” If we raise capital through strategic partnerships or other types of arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. There can be no assurance that we will be able to raise additional capital when needed. If we are unable to raise additional capital when needed, we will not be able to continue development of our product candidates or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, and we may be unable to pursue and complete the clinical trials that we would like to pursue and complete.

Our current financial and technical resources are not sufficient to develop all of the product candidates to which we hold licenses or options to license. This may impact the development efforts of our key portfolio candidates and any future candidates we may choose to develop. Due to our limited resources, we may be required to curtail clinical development programs and activities that might otherwise have led to more rapid progress of our product candidate, or product candidates that we may in the future choose to develop, through the regulatory and development processes. We may make incorrect determinations with regard to the indications and clinical trials on

which to focus the available resources that we do have. The decisions to allocate our research, management and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also cause us to miss valuable opportunities.

We expect to be heavily reliant on our ability to raise capital through capital market transactions. Due to our small public float, low market capitalization, limited operating history and lack of revenue, it may be difficult and expensive for us to raise additional capital.

We are heavily reliant on our ability to raise additional capital through the issuance of shares of our common stock or securities linked to our common stock. Our ability to raise capital will depend on a number of factors, many of which may not be favorable for raising capital, including the low trading volume and volatile trading price of our common stock, unfavorable market conditions or other market factors outside of our control, and the risk factors described elsewhere in this report, including those related to warrants we issued in February 2018. Even if we are able to raise additional capital, the cost of capital may be substantial due to our low market capitalization and our small public float, and the costs associated with raising capital and the effective cost of such capital for public companies like ours with a small public float may be more expensive when compared to the cost of capital for larger public companies. The terms of any funding we are able to obtain may not be favorable to us and may be highly dilutive to our stockholders, and debt financing, if available, may involve restrictive covenants. There can be no assurance that we will be able to raise additional capital when needed. The failure to obtain additional capital when needed would have a material adverse effect on our business.

We have been actively adding product candidates to our portfolio of innovative products for women's reproductive health, but we currently are not adequately capitalized to advance these product candidates through development.

Our business strategy is to license or otherwise acquire the rights to differentiated reproductive health product candidates primarily in the areas of contraception, vaginal health, sexual health, and fertility, and to take those candidates through advanced stages of clinical development. Taking product candidates through advanced stages of clinical development requires substantial capital and does not generate any income. We currently do not have the capital necessary to advance the product candidates to which we hold licenses and options to license. Executing our business strategy requires us to obtain additional capital to license or otherwise acquire rights to additional product candidates to grow and advance our portfolio and to take our product candidates through clinical development and eventually to commercialization or strategic partnership. Such capital may not be available to us, or even if it is, the cost of such capital may be high. See “—We have incurred significant losses since our inception and expect to incur continued losses in the future 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,” above. Based on our current operating plan, our current cash reserves are sufficient to fund operations for at least 12 months. Should we add additional product candidates to our portfolio or should our existing product candidates require testing or other capital-intensive procedures that we did not anticipate, our cash resources will be strained. We may be forced to obtain additional capital before reaching clinical milestones, when our stock price or trading volume or both are low, or when the general market for biopharmaceutical, medical device, or other life sciences companies is weak. Raising capital under any of these or similar scenarios, if we can raise any at all, may lead to significant dilution to our existing stockholders. If we are unable to raise additional capital when required and on acceptable terms, we will not be able to advance our product candidates or add additional product candidates to our portfolio or we will be required to delay, scale back or eliminate some or all our development programs or cease operations.

We depend on strategic collaborations with third parties to develop and commercialize our product candidates and we will not have control over a number of key elements relating to the development and commercialization of these product candidates if we are able to achieve such third-party arrangements.

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations or otherwise monetize these product candidates on acceptable terms, if at all.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise. Even if we are successful in entering into a strategic collaboration for one of our product candidates, our partner may fail to develop or effectively commercialize the product candidate because such partner:

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determines that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We also face competition in our search for partners from other biotechnology and pharmaceutical companies worldwide, many of whom are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting partners and entering into collaborations on acceptable terms for these product candidates or otherwise monetizing these product candidates, we may not be able to complete development of or obtain regulatory approval for such product candidates. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered.

The women's health care product candidates we are developing or may develop in the future are likely to face significant competition. In the event we receive regulatory approval for any of our product candidates, our ability to compete in the marketplace will be impacted by the efficacy and safety outcomes of our clinical trials.

Today, there are a variety of hormonal and non-hormonal contraceptive options available to women, including oral contraceptive pills and intrauterine devices, newer hormonal contraceptive products including implants, injectables, vaginal rings, patches, and hormonal intrauterine systems, and non-hormonal methods such as female condoms, novel diaphragms, and new methods of female sterilization. In surveys, women have said that the features they consider most important when selecting a contraceptive method are efficacy, ease-of-use and side effects. In order to have significant revenue potential as a new contraceptive product option, we believe Ovaprene must generate typical use efficacy outcomes (which are the expected rates of pregnancy protection once the product is used widely under every day circumstances) consistent with the most commonly used short-acting non-hormonal method, the condom, which is 82% effective and approaching that of a diaphragm which is approximately 88% effective. Clinical testing will also need to demonstrate that the device can be safely worn for multiple weeks. Should Ovaprene fail to generate the safety and efficacy data expected, our business prospects would be materially damaged.

Today's available options for treating FSAD consist primarily of over-the-counter products for vaginal lubrication. Although no products have been approved by the FDA specifically for the treatment of FSAD, we believe it is likely that new product candidates will be developed by others over time. Sexual arousal can be influenced by many different emotional and physiological factors and hence, our clinical trials must anticipate such factors in order to produce efficacious outcomes. SST-6007, our Topical Sildenafil product candidate, is designed to increase local blood flow to the genital tissue. Even if we are successful in increasing blood flow, the product may not lead to an increase in arousal or an improvement in the overall sexual experience in some women. If we fail to generate compelling clinical results from our trials, many women suffering from sexual arousal disorder may opt not to try SST-6007. If we fail to produce strong clinical outcomes, our ability to build a commercial market for SST-6007 will be materially impacted. See also "The patents and the patent applications related to SST-6007 cover topical formulations, processes and uses of sildenafil, and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors," below.

Today, a variety of options are available for the delivery of hormones to assist in the maintenance of pregnancy or to treat the symptoms of menopause. If approved, our intravaginal ring, or IVR, candidates will

compete with pills, patches and other hormonal delivery methods, and competing with those products may prove difficult given the current marketplace and established clinical practices. We believe our clinical trials for these candidates must demonstrate efficacy that is comparable to or better than existing products and also prove that the candidates would be more convenient. Some women may be uncomfortable with the notion of using an IVR and may never try our IVR products. If we fail to generate compelling clinical results from clinical trials, we may lack the data to generate a commercially viable product, which would harm our business.

If the Pear Tree Merger is consummated, we will acquire a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. Today's treatments for Vulvar and Vaginal Atrophy, or VVA, primarily consist of hormones, including localized estrogen. However, this therapeutic approach is often contraindicated for women diagnosed with, or at risk of recurrence of, hormone receptor positive breast cancer. The American College of Obstetricians and Gynecologists recommends a local non-hormonal approach for treating chronic conditions like VVA in these women. Although many women may be contraindicated for hormone use, particularly with respect to estrogen use, and there are no FDA-approved VVA treatments that have been specifically studied in these hormone receptor positive women, and therefore many doctors continue to prescribe, and many women continue to use, hormone-based treatments. If approved, our tamoxifen candidate for the treatment of VVA will compete with branded pills, vaginal inserts and other delivery methods for hormones. We believe our clinical trials must demonstrate comparable efficacy and safety with existing products that are currently used in VVA, including those that have not been studied in, but are nonetheless used in, breast cancer survivors.

Our business development strategy has included, and will likely continue to include, the acquisition of products, product licenses or other businesses. We may not be able to successfully manage such activities.

We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense. Strategic transactions, including the SST license agreement and the Juniper license agreement, both of which occurred between February 2018 and April 2018, and the Pear Tree Merger, if consummated, could subject us to a number of risks, including, but not limited to:

- our inability to appropriately evaluate the potential risks and uncertainties associated with a given transaction;
- our inability to effectively integrate a new technology, product and/or business, personnel, intellectual property or business relationships; and
- our inability to generate milestones or revenues from a strategic transaction sufficient to meet our objectives in undertaking the transaction.

We may underestimate development costs, timelines, regulatory approval challenges and commercial market opportunity for a strategic transaction that would cause us to fail to realize the anticipated value of the transaction. Any strategic transaction we may pursue may not produce the outcomes and benefits we originally anticipated, may result in costs that end up outweighing the benefits, and may adversely impact our financial condition and be detrimental to our company in general.

Risks Related to Clinical Development, Manufacturing and Commercialization

Our success will depend heavily on our ability to develop Ovaprene, SST-6007 and our other product candidates. Failure to develop these product candidates would likely adversely affect our business.

We currently have only two human clinical trial stage product candidates and our business depends on the successful clinical development and regulatory approval of each of these product candidates and/or our preclinical candidates, which may never occur. For example, Ovaprene will require substantial clinical testing in order to demonstrate that it is a safe and effective contraceptive option. Likewise, we will need to demonstrate that SST-6007 is a safe and effective option for women seeking treatment of FSAD. We have never received a regulatory approval for any product. Even if we are able to conduct clinical trials for these product candidates, we may be unable to obtain regulatory approval for any of them, which would have a material adverse effect on our business and operations. We rely on license agreements to license the product and technology rights of our current product candidates and may seek to license the product and technology rights to additional product candidates in women's reproductive health, but there can be no assurance we will be able to do so, or do so on favorable terms. There are

risks, uncertainties and costs associated with identifying, licensing and advancing product candidates through successful clinical development. Even if we were able to obtain the rights to additional product candidates, there can be no assurance that these candidates will ever be advanced successfully through clinical development.

Delays in the commencement or completion of clinical testing of our current and any other future product candidates we may seek to develop could result in increased costs and longer timelines and could impact our ability to ever become profitable. Clinical testing is time consuming and expensive and its outcome is uncertain.

We expect to commence a PCT clinical trial during the first half of 2018 in order to assess the safety and preliminary efficacy of Oviprene. In addition, pending authorization to do so from the FDA, we anticipate commencing a Phase 2b clinical trial for SST-6007 in the second half of 2018. All of our IVR product candidates have only been tested in preclinical studies, and we will need to obtain authorizations from the FDA as well as from the institutional review boards of universities and clinics, as appropriate, in order to commence clinical testing of those candidates in humans. The initiation and completion of these and other clinical trials for our product candidates may vary dramatically due to factors within and outside of our control, and the results from early clinical trials may not necessarily be predictive of results obtained in later clinical trials; even if results from early clinical trials are positive, we may not be able to confirm those results in future clinical trials. Further, clinical trials may not ever demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates. Any change in, or termination of, clinical trials could materially harm our business, financial condition, and results of operations.

Successful challenges to the FDA's interpretation of Section 505(b)(2) could impact the clinical development of SST-6007, our IVR product candidates and other candidates we may license or acquire and materially harm our business.

We intend to develop and seek approval for SST-6007 and our IVR product candidates pursuant to the FDA's Section 505(b)(2) regulatory pathway. If the Pear Tree Merger is consummated, we will acquire a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy, which we also intend to develop pursuant to the FDA's Section 505(b)(2) regulatory pathway. If the FDA determines that we may not use the 505(b)(2) pathway for the development of any of these candidates, then we would be required to seek regulatory approval via a "full" or "stand-alone" NDA under Section 505(b)(1). This would require us to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for SST-6007, any IVR product candidate and vaginal tamoxifen, if acquired, and the complications and risks associated with the respective product candidate or candidates, would likely substantially increase and would have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. As described above, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development programs for SST-6007, our IVR product candidates and vaginal tamoxifen, if acquired.

Although the FDA's longstanding position has been that it may rely upon prior findings of safety or effectiveness to support approval of a 505(b)(2) application, this policy has been controversial and subject to challenge in the past. In addition, notwithstanding the approval of an increasing number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. Even if we are able to utilize the Section 505(b)(2) regulatory pathway for one or more of our candidates, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, any delay resulting from our inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Obtaining regulatory approval is a lengthy, expensive and uncertain process and may not be obtained on a timely basis, or at all. The requirements for approval may change over time and our clinical development programs may not accurately anticipate all of our regulatory requirements.

Our success relies on third party suppliers, manufacturers and distributors, including multiple single source suppliers and manufacturers. We have no internal sales, marketing or distribution capabilities. Any failure by such third parties could negatively impact our business and our ability to develop and market any approved products.

We have a very small number of employees and no personnel dedicated to marketing, manufacturing or sales and distribution. If we receive the requisite regulatory approvals for one or more products, we expect to rely on third parties to manufacture such products, and as such we will be subject to inherent uncertainties related to product safety, availability and security. For example, our agreement with ADVA-Tec limits our ability to engage a manufacturing source for Ovaprene other than ADVA-Tec following regulatory approval. If ADVA-Tec fails to produce sufficient ring quantities to meet commercial demand, our ability to become profitable could be adversely impacted. To date, ADVA-Tec has only produced a small number of rings for clinical testing. Furthermore, for some of the key raw materials and components of Ovaprene, we have only a single source of supply, and alternate sources of supply may not be readily available.

Under the terms of the SST license agreement, Strategic Science will be responsible for obtaining supplies of SST-6007 for the Phase 2 clinical trials expected to be conducted in the United States. Thereafter, we will be responsible for obtaining pre-clinical, clinical and commercial supplies of SST-6007. Both ADVA-Tec and SST will need to rely on third party suppliers to provide the quantities required. We are responsible for sourcing supplies for our IVR product candidates, and our ability to develop and commercialize these products is dependent on complex supply chains. Additionally, if the Pear Tree Merger is consummated, we will be responsible for sourcing supplies related to the acquired proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy.

Moreover, we do not expect to control the manufacturing processes for the production of any current or future products or product candidates, all of which must be made in accordance with relevant regulations, and includes, among other things, quality control, quality assurance, compliance with cGMP and the maintenance of records and documentation. In the future, it is possible that our suppliers or manufacturers may fail to comply with FDA regulations, the requirements of other regulatory bodies or our own requirements, any of which would result in suspension or prevention of commercialization and/or manufacturing of our products or product candidates, including Ovaprene and SST-6007, suspension of ongoing research, disqualification of data or other enforcement actions such as product recall, injunctions, civil penalties or criminal prosecutions against us. Furthermore, we may be unable to replace any supplier or manufacturer with an alternate supplier or manufacturer on a commercially reasonable or timely basis, or at all.

If we were to outsource product distribution for any current or future product candidates, this outsourcing would also be subject to uncertainties related to these services including the quality of such services. For example, distributors may not have the capacity to supply sufficient product if demand increases rapidly or which may be subject to issues of force majeure. Further, we would be dependent on the distributors to ensure that the distribution process accords with relevant regulations, which includes, among other things, compliance with current good documentation practices, the maintenance of records and documentation, and compliance with applicable state laws that govern the licensure of distributors of prescription medical products. Failure to comply with these requirements could result in significant remedial action, including improvement of facilities, suspension of distribution or recall of product. Furthermore, we may be unable to replace any such distributor with an alternate distributor on a commercially reasonable or timely basis, or at all.

If we were to experience an unexpected loss of supply of, or if we fail to maintain relationships with our current suppliers, manufacturers, distributors or regulatory service providers, we may not be able to complete

development of Ovaprene, SST-6007, our IVR product candidates, vaginal tamoxifen, if acquired, or any other future product candidates, or to commercialize or market any products following approval, which would have a material and adverse effect on our business, financial condition, results from operation and prospects. Third-party suppliers, manufacturers, distributors or regulatory service providers may not perform as agreed or may terminate their agreements with us. Any significant problem that our suppliers, manufacturers, distributors or regulatory service providers experience could delay or interrupt our supply of materials or product candidates until the supplier, manufacturer, distributor or regulatory service provider cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available.

Additionally, any failure by us to forecast demand for finished product, including Ovaprene and SST-6007, and failure by us to ensure our distributors have appropriate capacity to distribute such quantities of finished product, could result in an interruption in the supply of certain products and a decline in sales of that product.

If we were to experience an unexpected loss of supply of, or if any supplier or manufacturer were unable to meet its demand for our product candidates, we could experience delays in research, planned clinical trials or commercialization. We might be unable to find alternative suppliers or manufacturers with FDA approval, of acceptable quality, in the appropriate volumes and at an acceptable cost. The long transition periods necessary to switch manufacturers and suppliers would significantly delay our timelines, which would materially adversely affect our business, financial conditions, results of operation and prospects.

Risks Related to Our Intellectual Property

Our failure to adequately protect or enforce our, or our licensor's, intellectual property rights could materially harm our proprietary position in the marketplace or prevent the commercialization of our current and potential future products.

Our success depends in part on our ability, and the ability of our licensor(s), to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technologies and products. The patents and patent applications relied upon by us are licensed to us by third parties. Our ability, or the ability of our licensor(s), to protect our product candidates from unauthorized use or infringement by third parties depends substantially on our abilities and the abilities of such licensors to obtain and maintain, or license, valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain or enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved.

Our patent strategy for the protection of Ovaprene includes in-licensing a patent family from ADVA-Tec, whose last claim expires in August 2028, but which could potentially be extended to August 2033 in the United States and Europe. Further, patent prosecution for the intellectual property incorporated into Ovaprene is entirely controlled by ADVA-Tec and we have little, if any, influence or control over such patent prosecution.

Our patent strategy for the protection of SST-6007 includes in-licensing a patent family from Strategic Science, whose last claim expires in 2031, but which could potentially be extended under the Hatch-Waxman Act in the United States.

With respect to patents related to SST-6007, Strategic Science will have the sole right, but not the obligation, to prepare, file, prosecute and maintain such patents. We will be responsible for the costs incurred to maintain and prosecute all such patents and we will be kept informed of all strategies. However, we will have little if any, influence or control over the implementation of the patent strategy.

With respect to patent rights related to our IVR product candidates, The General Hospital Corporation (known as MGH) has the sole right to prosecute and maintain its patent rights, and we have the right to prosecute and maintain Juniper's patent rights. We will be responsible for the costs incurred by MGH to maintain and prosecute such patents and we will be kept informed of all strategies. However, we will have little, if any, influence or control over MGH's implementation of the patent strategy.

If the Pear Tree Merger is consummated, we will acquire a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. With respect to patents related to vaginal tamoxifen, if acquired, we

anticipate we will have the right and obligation to prosecute and maintain the in-licensed patent rights in certain major markets, if possible.

There is a substantial backlog of patent applications at the United States Patent and Trademark Office. There can be no assurance that any patent applications relating to our products or methods will be issued as patents or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. We may not be able to obtain patent rights on products, treatment methods or manufacturing processes that we may develop or to which we may obtain license or other rights. Even if we do obtain patents, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. It is possible that no patents will be issued from any pending or future patent applications owned by us or licensed to us. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license, including the patents we have licensed from ADVA-Tec, Strategic Science, Juniper, and any other patents we may license in the future. Conversely, in the future we may be required to initiate litigation against third parties to enforce our intellectual property rights. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others or require us to cease selling our future products.

In addition, many other organizations are engaged in research and product development efforts that may overlap with our products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods we are developing or considering for development. These rights may prevent us from commercializing technology, or they may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and we cannot be sure that the patents underlying any such licenses will be valid or enforceable. As with other companies in the pharmaceutical industry, we are subject to the risk that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our intellectual property rights if such activities were conducted in the United States.

Our patents and intellectual property also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the United States or foreign jurisdictions, our business prospects could be substantially harmed. In addition, because of funding limitations and our limited cash resources, we may not be able to devote the resources that we might otherwise desire to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already-issued patents.

The patents and the patent applications covering SST-6007 are limited to specific topical formulations, processes and uses of sildenafil, and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors.

The active ingredient in our product candidate for FSAD, SST-6007, is sildenafil. Patent protection for this molecule has expired and generic oral formulation products are available for the treatment of male erectile dysfunction. As a result, a competitor that obtains the requisite regulatory approvals could offer products with the same active ingredient in a different formulation so long as the competitor does not infringe any process, use or formulation patents that we have developed.

Competitors may seek to develop and market competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for SST-6007 could be significantly harmed if competitors are able to develop and commercialize alternative formulations of sildenafil, including topical or other delivery mechanisms.

The patents and the patent applications covering our IVR product candidates cover the method of delivery and the device, and our market opportunity may be limited by the lack of patent protection for the active ingredients themselves and other formulations, delivery technology and systems that may be developed by competitors.

The active ingredients in our IVR product candidates include natural progesterone, estrogen and oxybutynin, and none of those ingredients are proprietary to us. As a result, we must compete with currently available products and any future products developed by competitors using same active ingredients in a different formulation or via a different delivery system. The commercial opportunity for our IVR product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations or better delivery approaches.

We have entered into an agreement pursuant to which we will acquire the right to develop a vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. If the Pear Tree Merger is consummated, the patents and the patent applications covering the use and delivery of vaginal tamoxifen, and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations, delivery technology and systems that may be developed by competitors.

If the Pear Tree Merger is consummated, we will acquire the right to develop a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. The active ingredient in this treatment for VVA, tamoxifen, will not be proprietary to us. As a result, we must compete with currently available products and any future products developed by competitors using the same active ingredient in a different formulation or via a different delivery system. The commercial opportunity for our product candidate for the treatment of VVA could be significantly harmed if competitors are able to develop and commercialize alternative formulations or better delivery approaches.

We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights. The situations in which we may become party to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights, or that one of our trademarks or trade names infringes the third party's trademark rights; in such case, we would need to defend against such proceedings. The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than us because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, including any rights licensed by us, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we were unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

With respect to Ovaprene, ADVA-Tec has the right, in certain instances, to control the defense against any infringement litigation arising from the manufacture or development (but not the sale) of Ovaprene. While our license agreement with ADVA-Tec requires ADVA-Tec to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Ovaprene.

With respect to SST-6007, we have the initial right to enforce the applicable licensed patents against infringers in the field of use where a third party is exploiting a topically applied pharmaceutical product that

contains at least one of the same active pharmaceutical ingredients as a licensed product, and Strategic Science will provide us with reasonable assistance (excluding financial assistance), at our expense. We also have the initial right to defend any claim initiated by any third party alleging that a licensed product developed or commercialized under the SST license agreement has infringed any third party intellectual property rights. While the SST license agreement requires Strategic Science to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop SST-6007.

With respect to our IVR product candidates, we have the first right to enforce the applicable licensed patents against third party infringers in the fields of pharmaceutical, therapeutic, preventative, diagnostic and palliative uses. If the Pear Tree Merger is consummated, we will acquire the right to develop a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. With respect to vaginal tamoxifen, we have the first right to enforce the applicable licensed patents against third party infringers in all fields.

Our exclusive, in-license agreements covering the critical patents and related intellectual property related to Ovaprene, SST-6007, IVR product candidates and other product candidates we may acquire or license impose significant monetary obligations and other requirements that may adversely affect our ability to execute our business plan. The termination of any of these in-license agreements could prevent us from developing and commercializing our drug candidates and may harm our business.

Our license agreements with ADVA-Tec, Strategic Science and Juniper include intellectual property rights to Ovaprene, SST-6007 and IVR product candidates, respectively. If the Pear Tree Merger is consummated, we will acquire intellectual property rights to a proprietary vaginal tamoxifen tablet for the treatment of vulvar and vaginal atrophy. These agreements require us, as a condition to the maintenance of our license and other rights, to make milestone and royalty payments and satisfy certain performance obligations. Our obligations under these in-license agreements impose significant financial and logistical burdens upon our ability to carry out our business plan. Furthermore, if we do not meet such obligations in a timely manner, and, in the case of milestone payment requirements, if we were unable to obtain an extension of the deadlines for meeting such payment requirements, we could lose the rights to these proprietary technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Further, there is no assurance that the existing license agreements covering the rights related to Ovaprene, SST-6007, and the IVR product candidates, or license agreements we enter into or acquire the rights to in the future, will not be terminated due to a material breach of the underlying agreements. With regard to the agreement covering Ovaprene, this would include a failure on our part to make milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities, or the loss of rights to the underlying intellectual property by any such licensors. With regard to the agreement covering SST-6007, this would include a failure to assume responsibility for suspended development activities within the requisite period, our failure to use commercially reasonable efforts in performing development activities, or the failure on our part to make milestone and royalty payments. With regard to the agreement covering our IVR product candidates, this would include a failure on our part to make milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities or the loss of rights to the underlying intellectual property by any such licensors. With regard to the agreement covering vaginal tamoxifen, if acquired, this would include our failure to use commercially reasonable efforts to bring a product to market.

Moreover, because some of our rights to Ovaprene, SST-6007 and the IVR product candidates are sublicensed pursuant to underlying agreements, there is no assurance that the existing license agreements covering the rights related to these product candidates will not be terminated due to termination of the underlying agreements, or due to the loss of rights to the underlying intellectual property by ADVA-Tec's, Strategic Science's or Juniper's licensors. There is no assurance that we will be able to renew or renegotiate license agreements on acceptable terms if our license agreements with ADVA-Tec, Strategic Science or Juniper the underlying agreements are terminated. We cannot guarantee that any license agreement will be enforceable. The termination of these license agreements or our inability to enforce our rights under these license agreements would materially and adversely affect our ability to develop and commercialize Ovaprene, SST-6007 and potential IVR product candidates.

All of the IVR product candidates licensed through our agreement with Juniper Pharmaceuticals are in preclinical stages of development.

Preclinical studies refer to a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected. Because of their early nature, preclinical product candidates tend to carry a higher risk of failure as compared with clinical-stage assets. Preclinical candidates must generate sufficient safety and efficacy data through in vitro studies, animal studies and a variety of tests before they can be considered appropriate for testing in humans. The development risks, timeline and cost of preclinical assets can be high because of the unknowns and absence of data. It can be difficult to identify relevant tests and animal models for preclinical studies. Even if the results from our preclinical studies are favorable, we still may not be able to advance the candidates into clinical trials. If we are unable to generate strong preclinical data, the IVR product candidates may never progress and may prove to be worthless.

Risks Related to Our Securities

Preclinical product candidates may not be valued by investors and may be difficult to fund.

Given their early stage of development and the lack of data, many preclinical assets are often perceived as having low valuations by investors and pharmaceutical companies. Our investment of time and resources in such assets may not be appreciated or valued. As a result, it may be difficult for us to fund such programs. If the IVR product candidates we licensed from Juniper fail to be valued, our stock price may be adversely affected.

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 Number	Filed Herewith
		Form	File Number	Date of Filing		
4.1	Form of Warrant to Purchase Common Stock	8-K	001-36395	02/13/2018	4.1	

Exhibit Number	Description of Exhibit	Incorporated by Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of Filing		
10.1Δ	License and Collaboration Agreement dated February 11, 2018 between Daré Bioscience, Inc., Strategic Science and Technologies-D, LLC and Strategic Science Technologies, LLC	10-K/A	001-36395	04/30/2018	10.1	
10.2	Common Stock Sales Agreement dated January 4, 2018 by and between Daré Bioscience, Inc. and H.C. Wainwright & Co., LLC	8-K	001-36395	01/04/2018	10.1	
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1#	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2#	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					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Label Linkbase Document					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X

Δ Portions of this document are subject to a confidential treatment request submitted to the SEC

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: May 14, 2018

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

Date: May 14, 2018

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

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

Date: May 14, 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: May 14, 2018

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

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended March 31, 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: May 14, 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 March 31, 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: May 14, 2018

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

