UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

OR

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

For the transition period from _____ to _____.

Commission file number 001-36395

DARÉ BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-4139823**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
11119 North Torrey Pines Road, Suite 200 La Jolla, CA	**92037**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 926-7655

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Indicate by check mark whether the registrant has submitted electronically 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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☒
Emerging growth company	☒			

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 provided 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 Exchange Act). Yes ☐ No ☒

Number of shares of the registrant's Common Stock, $0.0001 par value, outstanding on August 10, 2017: 6,047,165

DARÉ BIOSCIENCE, INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes statements with respect to Daré Bioscience, Inc. (a Delaware corporation previously known as Cerulean Pharma Inc.) and its subsidiaries ("we," "our," "us," the "Company" or "Daré"), which constitute "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "expect," "estimate," "intend," "plan," "project," "will be," "will continue," "will result," "seek," "could," "may," "might," "potential," "should," "target," "would," or any variations of such words or other words with similar meanings are intended to identify such forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, without limitation, statements regarding our future expectations; statements concerning product candidate development (including clinical and preclinical development), manufacturing and commercialization plans and timelines and related regulatory matters; any projections of financing needs, revenue, expenses, earnings or losses from operations, or other financial items; statements of the plans, strategies and objectives of management for future operations; any statements regarding safety and efficacy of product candidates; statements regarding our plans for partnerships, collaborations or other strategic transactions; any statements of expectation or belief; and any statements regarding other matters that involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to differ materially from results expressed in or implied by this Quarterly Report on Form 10-Q.

The risks, uncertainties and assumptions referred to above include risks that are described in Part II, Item 1A of this Quarterly Report on Form 10-Q in the section entitled "Risk Factors". You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We specifically disclaim any obligation to update these forward-looking statements in the future, except as required by law.

COMPLETION OF STOCK PURCHASE TRANSACTION

On July 19, 2017, all of the outstanding shares of capital stock of Daré Bioscience Operations, Inc., a private Delaware corporation, ("Private Daré") were purchased by Cerulean Pharma Inc. ("Cerulean") in accordance with the terms of a stock purchase agreement dated as of March 19, 2017 (the "Stock Purchase Agreement"), by and among Cerulean, Private Daré and the holders of capital stock and securities convertible into capital stock of Private Daré named therein (the "Private Daré Stockholders"). Pursuant to the Stock Purchase Agreement, each Private Daré Stockholder sold its shares of common stock in Private Daré to Cerulean in exchange for newly issued shares of Cerulean common stock. On July 19, 2017, Cerulean also completed the sale of its proprietary Dynamic Tumor Targeting™ Platform (the "Platform") to Novartis Institutes for BioMedical Research, Inc. ("Novartis") for $6.0 million. Following the closing of the transactions contemplated by the Stock Purchase Agreement (collectively, the "Stock Purchase Transaction") and the sale of the Platform, Cerulean changed its name to Daré Bioscience, Inc. As a result of the Stock Purchase Transaction, Private Daré became a wholly owned subsidiary of Daré Bioscience, Inc. and the Private Daré Stockholders became majority shareholders of Daré Bioscience, Inc. owning approximately 51% of the combined Company's outstanding shares of common stock. Except as described in Note 11, "Subsequent Events," the accompanying unaudited condensed consolidated financial statements do not give effect to the acquisition of Private Daré, the sale of the Platform to Novartis, or the issuance of the Company's common stock to the Private Daré Stockholders.

PRESENTATION AND REVERSE STOCK SPLIT

On July 20, 2017, we effected a 1 for 10 reverse stock split of our common stock (the "Reverse Stock Split"). All share and per share amounts of common stock, options and warrants in this Quarterly Report on Form 10-Q, including those amounts included in the accompanying condensed consolidated financial statements, have been restated for all periods to give retroactive effect to the Reverse Stock Split.

The condensed consolidated financial statements in this report have been labeled "Cerulean Pharma Inc." because they present financial information for periods prior to the effective time of the Stock Purchase Transaction and sale of the Platform to Novartis.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

CERULEAN PHARMA INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands except share data and par value)

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,244	$ 34,950
Accounts receivable, prepaid expenses, and other current assets	890	1,840
Total current assets	8,134	36,790
Property and equipment, net	17	668
Other assets	—	230
Total assets	$ 8,151	$ 37,688
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 660	$ 1,446
Accrued expenses	189	4,611
Current portion of loan payable	—	8,382
Current portion deferred revenue	2,500	2,500
Total current liabilities	3,349	16,939
Long-term liabilities:		
Loan payable, net of current portion	—	4,439
Deferred revenue	743	1,993
Other long-term liabilities	—	1,206
Total long-term liabilities	743	7,638
Commitments and contingencies		
Stockholders' equity:		
Preferred stock $0.01 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized, 2,903,172 and 2,893,718 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	215,213	213,791
Accumulated deficit	(211,154)	(200,680)
Total stockholders' equity	4,059	13,111
Total liabilities and stockholders' equity	$ 8,151	$ 37,688

See notes to unaudited condensed consolidated financial statements.

CERULEAN PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)
(in thousands except per share and share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ 642	$ —	$ 1,834	$ —
Operating expenses:				
Research and development	1,292	7,522	5,943	17,292
General and administrative	3,375	2,773	6,962	5,891
Gain on asset sale	—	—	(1,500)	—
Total operating expenses	4,667	10,295	11,405	23,183
Other income (expense):				
Interest income	20	25	53	41
Interest expense	—	(597)	(797)	(1,260)
Other income (expense)	(130)	8	(159)	1
Total other expense, net	(110)	(564)	(903)	(1,218)
Net loss attributable to common stockholders	$ (4,135)	$ (10,859)	$ (10,474)	$ (24,401)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (1.42)	$ (3.97)	$ (3.61)	$ (8.92)
Weighted-average common shares outstanding:				
Basic and diluted	2,903,139	2,736,397	2,902,865	2,736,330

See notes to unaudited condensed consolidated financial statements.

CERULEAN PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(in thousands)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (10,474)	$ (24,401)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,352	1,457
Noncash rent expense	(153)	134
Depreciation and amortization	80	127
Amortization of debt discount and deferred financing costs	610	242
Loss on disposal of property and equipment	177	4
Deferred revenue	(1,250)	—
Gain on asset sale	(1,500)	—
Changes in operating assets and liabilities:		
Accounts receivable, prepaid expenses and other current assets	950	(334)
Accounts payable	(785)	(458)
Accrued expenses	(4,423)	(1,272)
Net cash used in operating activities	(15,416)	(24,501)
Cash flows from investing activities:		
Purchases of property and equipment	—	(472)
Decrease in restricted cash	230	117
Proceeds from the sale of assets	1,894	—
Net cash provided by (used in) investing activities	2,124	(355)
Cash flows from financing activities:		
Proceeds from sale of common stock	70	41
Payments on loan payable	(13,077)	(3,900)
Payment of end of term charge on loan payable	(1,407)	—
Net cash used in financing activities	(14,414)	(3,859)
Net decrease in cash and cash equivalents	(27,706)	(28,715)
Cash and cash equivalents — Beginning of period	34,950	75,908
Cash and cash equivalents — End of period	$ 7,244	$ 47,193
Supplemental cash flow information — Interest paid	$ 269	$ 708

See notes to the unaudited condensed consolidated financial statements.

1. NATURE OF BUSINESS AND OPERATIONS

Nature of Business — On July 19, 2017, Cerulean Pharma Inc., now Daré Bioscience, Inc., a Delaware corporation ("Daré" or the "Company") completed its purchase of Daré Bioscience Operations, Inc., a Delaware corporation and private company ("Private Daré"), pursuant to the terms of that certain Stock Purchase Agreement, dated March 19, 2017, by and among the Company, Private Daré and the holders of capital stock and securities convertible into capital stock of Private Daré (the "Stock Purchase Agreement"). The stockholders of the Company approved the purchase of Private Daré and the other transactions contemplated by the Stock Purchase Agreement (collectively, the "Stock Purchase Transaction") on July 19, 2017. Except as described in Note 11, "Subsequent Events," the accompanying unaudited condensed financial statements do not give effect to the Stock Purchase Transaction. The historical financial statements have been labeled Cerulean Pharma Inc. for the purposes solely of this filing, which was the entity name in effect for the historical periods presented.

Prior to the Stock Purchase Transaction, the Company was an oncology-focused company applying its proprietary Dynamic Tumor Targeting™ Platform, (the "Platform"), to develop differentiated therapies. The Platform is designed to create nanoparticle-drug conjugates ("NDCs") with the aim of providing safer and more effective therapies for patients living with cancer. NDCs consist of anti-cancer therapeutics covalently linked to a proprietary polymer. On July 19, 2017, the Company completed the sale of the Platform to Novartis Institutes for BioMedical Research, Inc. ("Novartis") for $6.0 million. Following the Stock Purchase Transaction and sale of the Platform to Novartis, Daré is a healthcare company committed to the development and commercialization of innovative products in women's reproductive health. Daré's business strategy is to license the rights to novel reproductive health product candidates, some of which have existing clinical proof-of-concept data, and to take those candidates through advanced stages of clinical development. For more information regarding our business following the Stock Purchase Transaction, please see Part II, Item 5 of this Quarterly Report on Form 10-Q.

Basis of Presentation — The accompanying unaudited condensed consolidated financial statements present the historical results and financial position of Cerulean Pharma Inc. and its subsidiary, Cerulean Pharma Australia Pty Ltd, a wholly-owned Australian-based proprietary limited company, prior to the Stock Purchase Transaction and sale of the Platform to Novartis. These financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three and six months ended June 30, 2017, reflect the results of operations of the Company prior to the Stock Purchase Transaction and sale of the Platform to Novartis and are therefore not indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2017. For further information, refer to the consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission ("SEC") on March 31, 2017, and amended on April 28, 2017 and June 13, 2017 (the "2016 Form 10-K").

Following the closing of the Stock Purchase Transaction, which included the sale of the Platform to Novartis for $6 million, the Company believes that its existing resources will be sufficient to fund its planned operations for approximately two years.

Reverse Stock Split — on July 20, 2017, the Company effected a 1-for-10 reverse stock split of its outstanding common stock (the "Reverse Stock Split"). The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented. The shares of common stock retained a par value of $0.0001 per share. Accordingly, stockholders' equity reflects the Reverse Stock Split by reclassifying from common stock to additional paid-in capital an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

2. SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes to the significant accounting policies previously disclosed in the 2016 Form 10-K.

Recent Accounting Pronouncements — In November 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2016-18, "Statement of Cash Flows - Restricted Cash (Topic 230)". This new standard requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for

annual and interim reporting periods beginning after December 15, 2017, and required retrospective application. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued Accounting Standards Update 2016-15, “Statement of Cash Flows (Topic 230)” (“ASU 2016-15”). ASU 2016-15 provides guidance to clarify how cash payments for debt prepayment or debt extinguishment costs are to be classified in the statement of cash flows. The standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued Accounting Standards Update 2016-02, “Leases (Topic 842)” (“ASU 2016-02”), which provides new accounting guidance on leases. ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in ASU 2016-02 are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements and related disclosures.

In May 2014, the FASB issued Accounting Standards Update 2014-09 (ASC 606), “Revenue from Contracts with Customers” (ASU 2015-09), which affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. In August 2015, the FASB issued Accounting Standards Update 2015-14, “Revenue from Contracts with Customers” which defers the effective date of ASU 2014-09 for all entities by one year. ASU 2014-09, which has been codified with the Accounting Standards Codification as Topic 606, is now effective for public companies for annual reporting periods beginning after December 15, 2017, including interim periods within those reporting periods. ASC 606 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. In addition, ASC 606 provides guidance on accounting for certain revenue-related costs including, but not limited to, when to capitalize costs associated with obtaining and fulfilling a contract. ASC 606 provides companies with two implementation methods. Companies can choose to apply the standard retrospectively to each prior reporting period presented (full retrospective application) or retrospectively with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings of the annual reporting period that includes the date of initial application (modified retrospective application). Since ASU 2014-09 was issued, several additional Accounting Standards Updates have been issued and incorporated within ASC 606 to clarify various elements of the guidance. The Company plans to adopt this guidance on January 1, 2018. The Company has not yet determined whether it will utilize the full retrospective or the modified retrospective adoption method and continues to evaluate the impact that adoption will have on its consolidated financial statements.

3. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The Company computes diluted loss per common share after giving effect to the dilutive effect of stock options, warrants and shares of unvested restricted stock that are outstanding during the period, except where the inclusion of such securities would be antidilutive.

The Company has reported a net loss for all periods presented and, therefore, diluted net loss per common share is the same as basic net loss per common share.

The following potentially dilutive securities that were outstanding prior to the use of the treasury stock method have been excluded from the computation of diluted weighted-average shares outstanding, because the inclusion of such securities would have an antidilutive impact due to the losses reported (in common stock equivalent shares):

	As of June 30,	
	2017	2016
Options to purchase common stock	544,110	414,598
Warrants to purchase common stock	30,503	36,556

4. PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

	As of June 30, 2017	As of December 31, 2016
Laboratory equipment	$ —	$ 1,548
Computer equipment	100	371
Office furniture and equipment	—	66
Leasehold improvements	—	75
	100	2,060
Less accumulated depreciation and amortization	(83)	(1,392)
Property and equipment, net	$ 17	$ 668

On March 19, 2017, the Company entered into the Novartis Asset Purchase Agreement under which the Company agreed to sell and assign all of its right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Platform. The sale of such assets under the Novartis Asset Purchase Agreement, which required the approval of the holders of Cerulean Common Stock, resulted in substantially all of the Company's lab research activities terminating. As a result, in connection with the execution of the Novartis Asset Purchase Agreement, the Company determined to dispose of all of its lab equipment and initiated a program in March 2017 to locate a buyer and offer such equipment for sale which it completed in early April 2017. On May 31, 2017, the Company entered into a Lease Termination Agreement with its landlord to terminate its lease for office and laboratory space at the former headquarters at 35 Gatehouse Drive in Waltham, Massachusetts. Prior to the termination of its lease, which was effective on May 31, 2017, the Company had disposed of substantially all of the remaining computer equipment, office furniture and equipment, and leasehold improvements. The Company recorded a charge of $177,000 for the disposal of property and equipment which is included in other expense.

5. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	As of June 30, 2017	As of December 31, 2016
Accrued clinical trial costs	$ 25	$ 2,648
Accrued contract manufacturing expenses	—	226
Accrued compensation and benefits	44	1,080
Accrued interest	—	82
Other accrued expenses	120	575
Total accrued expenses	$ 189	$ 4,611

6. LOAN AGREEMENTS

On January 8, 2015, the Company entered into a loan and security agreement with Hercules to borrow up to $26.0 million (the "Hercules Loan Agreement"). The proceeds were used to repay the Company's then-existing term loan facility and for general corporate and working capital purposes. On March 17, 2017, the Company entered into a payoff letter with Hercules pursuant to which the Company agreed to pay off and thereby terminate the Hercules Loan Agreement. Pursuant to the payoff letter, on March 20, 2017, the Company paid a total of $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding under the Hercules Loan Agreement in repayment of its outstanding obligations under the Hercules Loan Agreement. This payoff amount included a final end of term charge to Hercules in the amount of $1.4 million, representing 6.7% of the aggregate original principal amount advanced by Hercules. Upon the payment of $12.4 million pursuant to the payoff letter, all outstanding indebtedness and obligations owed to Hercules under the Loan Agreement were deemed paid in full, and the Loan Agreement was terminated. At December 31, 2016, the Company had $13.1 million outstanding under the Hercules Loan Agreement and had accrued $1.1 million of the end of term charge.

In connection with the Hercules Loan Agreement, the Company issued to Hercules a warrant to purchase shares of the common stock of the Company at an exercise price of $60.50 per share. The warrant is exercisable for 17,190 shares of common stock. The warrant is exercisable until January 8, 2020. The Company estimated the fair value of the warrant for shares exercisable on the issue date in January 2015 to be $824,000. The value of the warrant was recorded as a discount to the loan and was being amortized to interest expense using the effective interest method over the term of the loan. The unamortized discount relating to the warrants, or $0.2 million, was expensed as interest expense upon repayment of the loan.

7. STOCK-BASED COMPENSATION

In March 2014, the Company's board of directors adopted and its stockholders approved the 2014 Stock Incentive Plan (the "2014 Plan") and the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective in April 2014.

Stock Options

The 2014 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards. A summary of stock option activity for employee, director and nonemployee awards under all stock option plans during the six months ended June 30, 2017 is presented below (Aggregate Intrinsic Value in thousands):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	402,028	$ 43.10	8.4	$ —
Granted	147,945	$ 8.20		
Exercised	—	—		
Forfeited	(5,863)	$ 42.09		
Outstanding at June 30, 2017	544,110	$ 33.62	7.9	$ —
Options exercisable at June 30, 2017	220,497	$ 47.92	7.6	$ —
Options vested and expected to vest at June 30, 2017	347,881	$ 40.10	8.1	$ —

The weighted-average per share grant date fair value of options granted during the six months ended June 30, 2017 and 2016 was $4.38 and $13.10, respectively.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions noted in the table below. Expected volatility for the Company's common stock was determined based on an average of the historical volatility of a peer-group of similar public companies. The Company has limited option exercise information, and as such, the expected term of the options granted was calculated using the simplified method that represents the average of the contractual term of the option and the weighted-average vesting period of the option. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free rate for periods within the contractual life of the option is based upon the U.S. Treasury yield curve in effect at the time of grant.

The Company has recorded stock-based compensation expense related to the issuance of stock option awards to employees of $440,000 and $690,000 for the three months ended June 30, 2017 and 2016, respectively, and $1.4 million and $1.4 million for the six months ended June 30, 2017 and 2016, respectively. There were no stock options granted to employees during the three months ended June 30, 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 June 30, 2016 and during the six months ended June 30, 2017 and 2016 are as follows:

	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Expected life	5.5 years	4.6 years	5.5-6.1 years
Risk-free interest rate	1.2%	1.8%	1.2%-1.9%
Expected volatility	61%	67%	61%
Expected dividend rate	—%	—%	—%

The Company recorded stock-based compensation expense related to nonemployee awards of $6,000 and $14,000 for the three months ended June 30, 2017 and 2016, respectively and $37,000 and $52,000 for the six months ended June 30, 2017 and 2016, respectively. The compensation expense related to nonemployee awards is included in the total stock-based compensation each year and is subject to re-measurement until the options vest. The fair value of the grants is being expensed over the vesting period of the options on a straight-line basis as the services are being provided. The Black-Scholes assumptions used to estimate fair value for the three and six months ended June 30, 2017 and 2016 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected life	9.1-9.8 years	9.0-9.6 years	4.6-9.8 years	6.9-9.7 years
Risk-free interest rate	2.2%-2.4%	1.7%-2.0%	1.8%-2.4%	1.7%-2.0%
Expected volatility	74%-78%	61%	67%-77%	60%-61%
Expected dividend rate	—%	—%	—%	—%

During the six months ended June 30, 2017, the Company granted nonemployee stock options to purchase 15,100 shares of the Company's common stock. There were no nonemployee stock option awards granted during the six months ended June 30, 2016. The weighted-average exercise price and the weighted-average grant date fair value of nonemployee stock options granted for the six months ended June 30, 2017 was $8.20 per share and $7.50 per share, respectively.

In March 2017, the Company extended the exercise period for all continuing employees' stock options to two years beyond their termination date. These option modifications were initially accounted for in the quarter ended March 31, 2017. The increase of stock-based compensation related to these modifications was $16,000 and $283,000 for the three and six months ended June 30, 2017, respectively.

Employee Stock Purchase Plan

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 the last day of the offering period, whichever is lower. Purchase dates under the ESPP occur on or about June 30 and December 31 of each year. The board of directors determined not to initiate a new offering period beginning January 1, 2017. There was no stock-based compensation related to the ESPP for the three and six months ended June 30, 2017. The stock-based compensation expense related to the ESPP was $12,000 and $24,000 for the three months and six months ended June 30, 2016, respectively.

8. FAIR VALUE MEASUREMENTS

The Company's financial instruments consist of cash equivalents, accounts payable, accrued expenses, and debt obligations. The carrying amount of accounts payable and accrued expenses are considered a reasonable estimate of their fair value, due to the short-term maturity of these instruments. The carrying amount of debt is also considered to be a reasonable estimate of its fair value based on the short term nature of the debt and because the debt bears interest at the prevailing market rate for instruments with similar characteristics.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs.

The accounting standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 — Quoted prices (unadjusted) in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the 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.

A summary of the financial assets and liabilities that are measured on a recurring basis at fair value as of June 30, 2017 and December 31, 2016, is as follows (in thousands):

	Carrying Value	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
June 30, 2017				
Money market funds	$ 7,014	$ —	$ 7,014	$ —
December 31, 2016				
Money market funds	$ 34,950	$ —	$ 34,950	$ —

The Company believes that its debt obligations bear interest at rates which approximate prevailing market rates for instruments with similar characteristics and, accordingly, the carrying values for these instruments approximate fair value. The Company's debt obligations are Level 2 measurements in the fair value hierarchy.

The Company's money market funds have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported trades, executable bid and asked prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security. The Company is ultimately responsible for the consolidated financial statements and underlying estimates. Accordingly, the Company assesses the reasonableness of the valuations provided by the third-party pricing services by reviewing actual trade data, broker/dealer quotes and other similar data, which are obtained from quoted market prices or other sources.

No transfers between levels occurred during the periods presented.

9. REVENUE

In October 2016, the Company entered into a research collaboration agreement with Novartis pursuant to which the Company granted to Novartis certain exclusive, world-wide licenses to the Company's intellectual property relating to its platform technology and know-how. Under the collaboration, the Company and Novartis agreed to collaborate, over an initial research term of two years, with respect to the pre-clinical development of nanoparticle drug conjugates comprised of the Company's proprietary polymer covalently linked to Novartis-selected active pharmaceutical ingredients for up to five targets to be agreed upon by the Company and Novartis. In October 2016, the Company received a $5.0 million upfront payment under the collaboration which it will recognize on a straight-line basis over the initial term of the collaboration. The Company will also receive funding from Novartis for up to five full-time employees of the Company to be engaged in activities under the collaboration during the research term. For the three and six months ended June 30, 2017, the Company recognized revenue of $625,000 and $1.3 million, respectively, in connection with the upfront fee, and $17,000 and $584,000, respectively, in connection with the funding for activities performed under the collaboration during the research term.

10. RESTRUCTURING

On March 19, 2017, the Company entered into retention agreements with certain executive officers. These retention agreements supersede the provisions of such executive officers' employment agreements and retention letters with the Company providing for post-separation benefits, and provide for certain lump sum payments ranging from six to 18 months of salary, plus health and dental insurance coverage, while also providing the covered executives with a cash bonus upon completion of a change in control. The Company paid $1.1 million under the terms of the retention agreements on March 31, 2017 which was recorded as a prepaid expense. Under the terms of the retention agreements, the retention payments are earned upon continued employment with the Company for the retention period of three or six months, as specified in the retention agreements, unless earlier released by the Company. During the three months ended June 30, 2017, $923,000 of the retention payments was earned and recognized in operating expenses. In addition, under the terms of the retention agreements, the Company may be required to pay up to an additional $1.6 million of change in control and severance payments.

On March 19, 2017, the board of directors approved an amendment of the Company's existing options to provide that, notwithstanding each such option's original vesting schedule and notwithstanding that the option holder's service with the Company may have terminated prior to the closing of a change in control, effective immediately prior to a change in control, the vesting schedule of each such option would be accelerated in full so that all shares would immediately become vested and exercisable, or, if shorter, in accordance with the original vesting schedule set forth in the applicable option award agreement. The Board also approved

an amendment of all existing options to provide that, notwithstanding each such option's original terms effective on the date thereof, the period during which such option holder may exercise his or her stock options that are vested on the date of his or her termination of service with the Company would be extended until the date two (2) years following the date the option holder ceased providing service to the Company, provided that in no event may such option be exercised following the end of the original term of such option.

11. SUBSEQUENT EVENTS

Stock Purchase, Reverse Stock Split, Name Change, and Related Transactions

As described in Note 1, "Nature of Business and Operations," on July 19, 2017, the Company completed the stock purchase of Private Daré. Pursuant to the terms of the Stock Purchase Agreement, Cerulean issued shares of its common stock to Private Daré stockholders at an exchange ratio of 2.029969 shares of its common stock for each one share of Private Daré common stock outstanding before giving effect to the Reverse Stock Split. In addition, the Company assumed all outstanding options to purchase shares of Private Daré common stock, which options converted into options to purchase shares of its common stock, appropriately adjusted based on the exchange ratio. As a result of such issuance of shares, the stockholders of Private Daré became the majority stockholders of the Company.

The Stock Purchase Transaction will be accounted for as a "reverse merger" under the acquisition method of accounting for business combinations with Private Daré treated as the accounting acquirer. Private Daré was determined to be the accounting acquirer based upon the terms of the Stock Purchase Transaction and other factors, such as relative voting rights and the composition of the combined company's board of directors and senior management. All of the assets and liabilities of the Company will be recorded at their respective fair values as of the acquisition date and consolidated with those of Private Daré. Transaction costs will be expensed as incurred.

Given the timing of the closing of the Stock Purchase Transaction, the purchase accounting is incomplete at this time. As such, it is not practicable for the Company to disclose the allocation of purchase price to assets acquired and liabilities assumed and pro forma revenues and earnings of the combined entity. The fair value of the consideration transferred in the Stock Purchase Transaction will be measured using the closing trading price of the Company's common stock on July 19, 2017, the closing date of the Stock Purchase Transaction. This information will be included in the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2017 and in a Form 8-K/A to be filed with the SEC.

On July 19, 2017, the Company completed the sale to Novartis of all of its right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Platform pursuant to the Novartis Asset Purchase Agreement dated March 19, 2017. At the closing of the transaction, Novartis paid the Company $6.0 million.

On July 20, 2017, the Company effected the Reverse Stock Split and changed its name to Daré Bioscience, Inc.

Prior to the closing of the Stock Purchase Transaction, the Company's stock was listed on The Nasdaq Capital Market under the ticker symbol "CERU." On July 20, 2017, the Company's common stock commenced trading on The Nasdaq Capital Market (on a Reverse Stock Split-adjusted basis) under the ticker symbol "DARE."

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and their notes appearing elsewhere in this quarterly report. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this quarterly report.

In the following discussion the terms "Daré," "we," "our," "us" or the "Company" refer to Daré Bioscience, Inc., formerly known as Cerulean Pharma Inc., a Delaware corporation.

Financial Presentation

The condensed consolidated financial statements in this report have been labeled "Cerulean Pharma Inc." because they present financial information for periods prior to the effective time of the Stock Purchase Transaction and sale of the Platform to Novartis. Likewise, in this Management's Discussion and Analysis of Financial Condition and Results of Operations, in regard to discussion of the financial condition and results of operations at and for historical periods, we refer to our company as "Cerulean".

Overview

On March 19, 2017, Cerulean entered into a stock purchase agreement with Daré Bioscience Operations, Inc. ("Private Daré") and the holders of capital stock and securities convertible into capital stock of Private Daré (the "Stock Purchase Agreement"). The stockholders of Cerulean approved the purchase of Private Daré and the other transactions contemplated by the Stock Purchase Agreement (collectively, the "Stock Purchase Transaction") on July 19, 2017.

Pursuant to the terms of the Stock Purchase Agreement, Cerulean issued shares of its common stock to Private Daré stockholders at an exchange ratio of 2.029969 shares of our common stock for each one share of Private Daré common stock outstanding before giving effect to the Reverse Stock Split. In addition, we assumed all outstanding options to purchase shares of Private Daré common stock, which options converted into options to purchase shares of our common stock, appropriately adjusted based on the exchange ratio. Immediately after the closing, former stockholders of Private Daré collectively held approximately 51% of the outstanding shares of the combined Company and former stockholders of the Company held approximately 49% of the outstanding shares of the combined Company. No fractional shares of common stock were issued in connection with the transaction.

In connection with the completion of the Stock Purchase Transaction on July 19, 2017, we filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation, effecting the Reverse Stock Split as of July 20, 2017. As a result of the Reverse Stock Split, each ten shares of our common stock issued and outstanding immediately prior to the Reverse Stock Split were automatically combined into and became one share of common stock. No fractional shares were issued as a result of the Reverse Stock Split and any stockholder who otherwise would have been entitled to receive fractional shares, received cash in an amount, without interest, determined by multiplying such fraction of a share by $6.56, the closing price of a share of our common stock on the Nasdaq Stock Market on July 19, 2017, after giving effect to the Reverse Stock Split. Also, as a result of the Reverse Stock Split, the per share exercise price of, and the number of shares of common stock underlying, our stock options, warrants and other derivative securities outstanding immediately prior to the Reverse Stock Split were automatically proportionally adjusted based on the one-for-ten split ratio in accordance with the terms of such options, warrants or other derivative securities, as the case may be.

After giving effect to the Stock Purchase Transaction and the Reverse Stock Split, we have approximately 6.0 million shares of common stock outstanding. The Reverse Stock Split did not alter the par value of our common stock or modify any voting rights or other terms of the common stock.

Following these transactions, we changed our name from Cerulean Pharma Inc. to Daré Bioscience, Inc. and our stock began trading on the Nasdaq Capital Market under the symbol "DARE" on July 20, 2017.

Upon completion of the Stock Purchase Transaction, Christopher D.T. Guiffre, Alan L. Crane, Paul A. Friedman, William T. McKee, Stuart A. Arbuckle, David R. Parkinson and David R. Walt resigned from the Company's board of directors (the "Board"), while Roger L. Hawley, Robin J. Steele and Sabrina Martucci Johnson were appointed to the Board. In accordance with the Stock Purchase Agreement, the Board and its committees were reconstituted, with Susan L. Kelley, M.D. appointed as a Class I director of the Company whose term expires at the Company's 2018 annual meeting of stockholders, William H. Rastetter, Ph.D. and Robin J. Steele appointed as Class II directors of the Company whose terms expire at the Company's 2019 annual meeting of stockholders and Sabrina Martucci Johnson and Roger L. Hawley appointed as Class III directors of the Company whose terms expire at the Company's 2020 annual meeting of stockholders (with Mr. Hawley appointed to serve as Chairman of the Board). On July 19, 2017, in connection with the Stock Purchase Transaction, Christopher D.T. Guiffre. and Gregg Beloff resigned their positions as the

Company's Chief Executive Officer and Interim Chief Financial Officer, respectively, and Sabrina Martucci Johnson and Lisa Walters-Hoffert were appointed President and Chief Executive Officer and Chief Financial Officer of the Company, respectively.

On March 19, 2017, Cerulean also entered into an asset purchase agreement (the "Novartis Asset Purchase Agreement") with Novartis. Under the Novartis Asset Purchase Agreement, it agreed to sell and assign to Novartis all of its right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Platform. Cerulean refers to this transaction as the Novartis Transaction. On July 19, 2017, Cerulean completed the sale of the Platform to Novartis for $6.0 million.

Business After the Stock Purchase Transaction

Daré is a healthcare company committed to the development and commercialization of innovative products in women's reproductive health. We have identified areas within this market segment that remain underserved and believe they offer opportunities to generate value. This segment encompasses a broad spectrum of categories, including contraception, vaginal health, pain and fertility. Our goal is to develop a portfolio of clinical candidates that expands options, improves outcomes and facilitates ease of use across multiple categories within women's reproductive health.

The contraceptive market in particular represents an interesting segment for Daré. Since the approval of the birth control pill by the U.S. Food and Drug Administration ("FDA") in 1960, most contraception innovation has focused on the use of hormones. Little innovation has occurred to create new non-hormonal options, leaving a void in the method mix and creating a potential opportunity. Today's non-hormonal alternatives include condoms, diaphragms, and spermicides, all of which require intervention at the time of intercourse and most of which have marginal efficacy. There is a need for something better.

Our first product candidate is Ovaprene®, a clinical stage, non-hormonal contraceptive ring intended to provide protection over multiple weeks. If approved, it would represent a new category of contraception. Ovaprene® has a custom intravaginal ring design, with a permeable mesh in the center of the ring that creates a partial barrier to sperm, and a mechanism to release locally acting spermiostatic agents through the ring. The unique combination of these two complementary approaches seeks to produce attractive contraceptive efficacy outcomes that are consistent with the most effective barrier option, the diaphragm, and short-acting hormonal options (oral pill, patches and vaginal ring) that provide 88-91% effectiveness in typical use. Typical use refers to effectiveness experienced among all couples who use the method, including inconsistent and incorrect use.

In a pilot postcoital test ("PCT") clinical trial conducted in 21 women and published in the Journal of Reproductive Medicine in 2009, Ovaprene® demonstrated the following:

- Ability to immobilize sperm and prevent their progression into the cervical mucus,
- Acceptability of the device to both partners, and
- No, reported, serious adverse events.

Daré is currently in discussions regarding other product candidates that meet our selection criteria. We are also exploring co-development opportunities with non-profit partners and foundations as a way to leverage their tremendous investment capacity and breadth of product candidates. Daré is committed to identifying, licensing and developing candidates that expand options, improve outcomes, and enhance safety for women across the broad spectrum.

For more information regarding our business following the Stock Purchase Transaction, please see Part II, Item 5 of this Quarterly Report on Form 10-Q.

Business Before the Stock Purchase Transaction

Prior to the Stock Purchase Transaction, Cerulean was an oncology-focused company applying its Platform to develop differentiated therapies.

The Platform is designed to create nanoparticle-drug conjugates ("NDCs") with the aim of providing safer and more effective therapies for patients living with cancer. NDCs consist of anti-cancer therapeutics, or payloads, covalently linked to a proprietary polymer. An important goal for all drugs is to maximize the net clinical benefit by increasing the desired therapeutic effect while reducing adverse effects. This is especially difficult with drugs used to treat cancer, where the goal is to destroy or inhibit growth of cancer cells without damaging healthy cells. Cerulean believes NDCs concentrate their anti-cancer payloads inside tumor cells while sparing normal tissue because they are small enough to pass through the leaky pores of new blood vessels in tumors as an entry portal into tumor tissue, but are too large to pass through the pores of healthy blood vessels. Once inside tumors, Cerulean believes NDCs are actively taken up into tumor cells where they slowly release their anti-cancer payloads, providing a durable inhibition of their targets.

Based on their properties and design, NDCs have the potential to enable synergistic combination therapies that can offer better tolerability and efficacy. Cerulean believes that better tolerability can be achieved through the preferential accumulation of the NDC in the tumor cells while better efficacy can be achieved by combining drugs that have different and complementary mechanisms of action. Cancer is a multi-faceted disease that is rarely adequately addressed by one therapy. Tumor cells are genetically diverse and can rapidly resist and ultimately overcome a single-agent therapy by modulating various adaptive pathways; however, if multiple drugs simultaneously shut down multiple adaptive pathways, there is a greater chance of achieving favorable disease responses for an extended period of time.

The Platform generated two clinical-stage NDCs. The first clinical candidate generated by the Platform, CRLX101, is an NDC with a camptothecin payload. Camptothecin is a potent topoisomerase 1 inhibitor that was too toxic to develop in the clinic; however, CRLX101 reduces the toxicities associated with this highly potent agent, while increasing the payload concentration in tumors. The second clinical candidate generated by the Platform, CRLX301, is an NDC with a docetaxel payload. Docetaxel is a commercially successful oncology drug that suffers from significant toxicities. Cerulean sold both clinical candidates in March 2017.

In August 2016, Cerulean announced top-line results from its Phase 2, randomized, multi-center clinical trial of CRLX101 in combination with Avastin in the treatment of patients with advanced renal cell carcinoma ("RCC"). Cerulean refers to this trial as the RCC Trial. The RCC Trial was conducted at 43 sites in the United States and South Korea, and enrolled 115 patients with RCC who progressed through two or three prior lines of therapy. Patients were randomized to receive CRLX101 in combination with Avastin or investigator's choice standard of care ("SOC") therapy. The primary endpoint was progression free survival ('PFS") in the clear cell population assessed by independent radiological review. Secondary endpoints included overall response rate, duration of response and overall survival. The study demonstrated no statistically significant difference in median PFS and objective response rate for the CRLX101 and Avastin combination compared to SOC. Based on these top-line results, Cerulean submitted a letter to the FDA voluntarily surrendering the Fast Track Designation in metastatic RCC it received in April 2015. Cerulean discontinued development of CRLX101 in this indication.

In October 2016, Cerulean entered into a research collaboration agreement with Novartis. Under the collaboration agreement, Cerulean agreed to create NDC candidates using the Platform and Novartis-selected active pharmaceutical ingredients, and Novartis agreed to be responsible for the development and commercialization of NDC products resulting from the collaborative research efforts. The initial research term of the collaboration agreement is two years which may be extended for up to two additional one-year terms. Cerulean received a $5.0 million upfront payment under the collaboration agreement, and was entitled to receive additional research, development, regulatory and sales milestone payments, as well as royalties on net sales of any NDC product commercialized by Novartis. In addition, Cerulean was entitled to receive funding for up to five full-time employees to be engaged in activities under the collaboration during the research term. This collaboration agreement was superseded by the Novartis Asset Purchase Agreement.

On May 31, 2017, Cerulean entered into a lease termination agreement with its landlord to terminate its lease for office and laboratory space at 35 Gatehouse Drive in Waltham, Massachusetts. Pursuant to the terms of the agreement, Cerulean made an early termination payment of approximately $427,000 and the termination was effective as of May 31, 2017.

On March 19, 2017, Cerulean entered into an Asset Purchase Agreement with BlueLink Pharmaceuticals, Inc. ("BlueLink"), a subsidiary of NewLink Genetics Corporation. Cerulean refers to this as the BlueLink Asset Purchase Agreement. Under the BlueLink Asset Purchase Agreement Cerulean sold and assigned to BlueLink all of its right, title and interest in and to its clinical product candidates CRLX101 and CRLX301 (the "Products"). Cerulean also transferred and assigned to BlueLink the accompanying intellectual property rights and know-how to the Products. On March 21, 2017, BlueLink paid the purchase price of $1.5 million.

On March 17, 2017, Cerulean entered into a payoff letter with Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.) ("Hercules"), pursuant to which it agreed to pay off and thereby terminate its Loan and Security Agreement dated as of January 8, 2015 (the "Hercules Loan Agreement") with Hercules as lender. Pursuant to the payoff letter, Cerulean paid, on March 20, 2017, a total of $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding under the Hercules Loan Agreement in repayment of its outstanding obligations under the Hercules Loan Agreement. This payoff amount included a final end of term charge to Hercules in the amount of $1.4 million, representing 6.7% of the aggregate original principal amount advanced by Hercules. Upon the payment of the $12.4 million pursuant to the payoff letter, all outstanding indebtedness and obligations to Hercules under the Hercules Loan Agreement were deemed paid in full, and the Hercules Loan Agreement was terminated.

As of June 30, 2017, Cerulean had an accumulated deficit of $211.2 million. Cerulean incurred net losses of $10.5 million and $24.4 million for the six months ended June 30, 2017 and 2016, respectively.

Critical Accounting Policies

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as "critical" because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

The critical accounting policies Cerulean identified in its most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016 related to accrued expenses and stock-based compensation. In the six months ended June 30, 2017, there were no changes to the significant accounting policies identified in Cerulean's most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016. It is important that the discussion of Cerulean's operating results that follow be read in conjunction with the critical accounting policies disclosed in its Annual Report on Form 10-K, as filed with the SEC on March 31, 2017 and amended on April 28, 2017 and June 13, 2017.

In connection with the Stock Purchase Transaction, we will adopt the significant accounting policies of Private Daré, which are included in Private Daré's consolidated financial statements for the years ended December 31, 2016 and December 31, 2015 and Private Daré's interim condensed consolidated financial statements for the three months ended March 31, 2017 and March 31, 2016, both of which are included in the Company's definitive proxy filed with the SEC on May 26, 2017.

Results of Operations

The following discussion of the Company's results of operations refers to the Company's results of operations prior to the Stock Purchase Transaction, and are not indicative of the Company's future results of operations. The results have been labeled Cerulean because they present financial information for periods prior to the effective time of the Stock Purchase Transaction and sale of the Platform to Novartis.

Comparison of Three Months Ended June 30, 2017 and 2016 (Unaudited)

The following table summarizes Cerulean's consolidated results of operations for the three months ended June 30, 2017 and 2016, together with the changes in those items in dollars and as a percentage (in thousands, except percentages):

	Three Months Ended June 30,		Change	
	2017	2016	Dollar	%
Revenue	$ 642	$ —	$ 642	—
Operating expenses:				
Research and development	1,292	7,522	(6,230)	(83)%
General and administrative	3,375	2,773	602	22%
Loss from operations	(4,025)	(10,295)	6,270	(61)%
Total other expense, net	(110)	(564)	454	(80)%
Net loss	$ (4,135)	$ (10,859)	$ 6,724	(62)%

Revenue. Revenue for the three months ended June 30, 2017 was $0.6 million compared to no revenue for the three months ended June 30, 2016. Revenue for the three months ended June 30, 2017 was from the Novartis collaboration agreement.

Research and development. Research and development expense for the three months ended June 30, 2017, was $1.3 million compared to $7.5 million for the three months ended June 30, 2016, a decrease of $6.2 million, or 83%. The decrease in research and development expenses is primarily attributable to a decrease of $4.5 million in external expenses, $1.7 million in salary and benefits expenses, and $0.5 million in facility and operating supplies and expense, partially offset by restructuring costs of $0.6 million. The decrease in external expenses is primarily attributable to a decrease of $2.1 million in chemistry, manufacturing, and controls, or CMC, expenses combined with a decrease of $1.8 million in expenses associated with clinical trials. The decrease in CMC expenses is attributable to the absence of manufacturing activities in the second quarter of 2017 compared to increased activity in the second quarter of 2016 to support then-ongoing and future clinical development. The decrease in clinical trials expenses reflects the sale of the clinical product assets and assignment of the related ongoing clinical trial contracts to BlueLink in March 2017.

General and administrative. General and administrative expense for the three months ended June 30, 2017, was $3.4 million compared to $2.8 million for the three months ended June 30, 2016, an increase of $0.6 million, or 22%. The increase in general and administrative costs was primarily attributable to an increase in external expenses of $0.7 million, restructuring costs of $0.3 million and the lease termination fee of $0.4 million partially offset by a decrease in salary and benefits expense of $0.6 million and a decrease in other general and administrative expenses of $0.2 million. The increase in external expenses included an increase in legal fees of $0.6 million and an increase in accounting fees of $0.2 million primarily associated with the 2017 strategic transactions.

Other expense, net. Other expense, net was $0.1 million for the three months ended June 30, 2017 compared to $0.6 million for the three months ended June 30, 2016, a decrease of $0.5 million or 80%. For the three months ended June 30, 2017 other expense, net, reflected a charge for the loss on disposal of property and equipment of $0.2 million partially offset by interest income of $0.1 million. For the three months ended June 30, 2016 other expense, net, was primarily interest expense associated with the Hercules Loan Agreement, including $0.1 million for the amortization of debt discount and deferred financing costs.

Comparison of Six Months Ended June 30, 2017 and 2016 (Unaudited)

The following table summarizes Cerulean's consolidated results of operations for the six months ended June 30, 2017 and 2016, together with the changes in those items in dollars and as a percentage (in thousands, except percentages):

	Six Months Ended June 30,		Change	
	2017	2016	Dollar	%
Revenue	$ 1,834	$ —	$ 1,834	—
Operating expenses:				
Research and development	5,943	17,292	(11,349)	(66)%
General and administrative	6,962	5,891	1,071	18%
Gain on sale of asset	(1,500)	-	(1,500)	—
Loss from operations	(9,571)	(23,183)	14,683	(63)%
Total other expense, net	(903)	(1,218)	315	(26)%
Net loss	$ (10,474)	$ (24,401)	$ 14,998	(61)%

Revenue. Revenue for the six months ended June 30, 2017 was $1.8 million compared to no revenue for the six months ended June 30, 2016. Revenue for the six months ended June 30, 2017 was from the Novartis collaboration agreement.

Research and development. Research and development expense for the six months ended June 30, 2017, was $5.9 million compared to $17.3 million for the six months ended June 30, 2016, a decrease of $11.3 million, or 66%. The decrease in research and development expenses is primarily attributable to a decrease of $8.2 million in external expenses, $2.8 million in salary and benefits expenses, and $0.9 million in travel expense and operating supplies and expense, partially offset by restructuring costs of $0.6 million. The decrease in external expenses is primarily attributable to a decrease of $4.8 million in CMC expenses combined with a decrease of $2.9 million in clinical trial and regulatory expenses. The decrease in CMC expenses is attributable to the absence of manufacturing activities in the first half of 2017 compared to increased activity in the first half of 2016 to support then-ongoing and future clinical development. The decrease in clinical trials expenses reflects the decrease in clinical activity as the Company winds down clinical operations and transfers the clinical assets and related ongoing clinical trial contracts to BlueLink.

General and administrative. General and administrative expense for the six months ended June 30, 2017, was $7.0 million compared to $5.9 million for the six months ended June 30, 2016, an increase of $1.1 million, or 18%. The increase in general and administrative costs was primarily attributable to an increase in external expenses of $1.8 million, restructuring costs of $0.3 million and the lease termination fee of $0.4 million partially offset by a decrease in salary and benefits expense of $1.0 million and a decrease in other general and administrative expenses of $0.4 million. The increase in external expenses included an increase in legal fees of $1.9 million and an increase in accounting fees of $0.2 million primarily associated with the 2017 strategic transactions partially offset by a decrease in other consulting expense of $0.3 million.

Gain on sale of asset. Gain on asset sale reflects the proceeds from the sale of the Products to BlueLink for which there was no corresponding value on the balance sheet. Under the BlueLink Asset Purchase Agreement the Company sold and assigned to BlueLink all of its right, title and interest in and to the Products. The Company also transferred and assigned to BlueLink the accompanying intellectual property rights and know-how to the Products.

Other expense, net. Other expense, net was $0.9 million for the six months ended June 30, 2017 compared to $1.2 million for the six months ended June 30, 2016, a decrease of $0.3 million or 26%. For the six months ended June 30, 2017 other expense, net, was primarily interest expense associated with repayment of the Hercules Loan Agreement combined with a charge for the loss on disposal of property and equipment of $0.2 million. Interest expense associated with the repayment of the Hercules Loan Agreement includes $0.2 million interest paid, $0.4 million for the remaining balance accrued for the end of term charge and $0.2 million for the write-off of the unamortized balance of debt discount and deferred financing charges. For the six months ended June 30, 2016 other expense, net, was primarily interest expense associated with the Hercules Loan Agreement, including $0.2 million for the amortization of debt discount and deferred financing costs.

Liquidity and Capital Resources

From Cerulean's incorporation through June 30, 2017, it raised an aggregate of $236.6 million to fund its operations, of which $84.2 million was from the sale of preferred stock in private placements, $59.9 million was from the initial public offering, $37.2 million was from its follow-on offering in April 2015, $17.3 million was from the sale of convertible promissory notes, $31.0 million was from borrowings under loan and security agreements, $1.0 million was from the private placement of Cerulean's common stock to Hercules, $1.0 million was from the initial purchase by Aspire under the at-the-market equity facility, and $5.0 million was from the upfront payment under the collaboration agreement with Novartis. As of June 30, 2017, Cerulean had cash and cash equivalents of $7.2 million.

Indebtedness

Hercules Loan Agreement. On January 8, 2015, Cerulean entered into the Hercules Loan Agreement and borrowed $15.0 million from Hercules. A portion of those proceeds were used to repay its outstanding indebtedness under the Lighthouse Loan Agreement. The Hercules Loan Agreement provided for up to three separate tranches of borrowings, the first of which was funded in the amount of $15.0 million on January 8, 2015. On November 24, 2015, Cerulean drew a second tranche in the amount of $6.0 million.

Cerulean's indebtedness under the Hercules Loan Agreement was scheduled to mature on July 1, 2018. Each advance under the Hercules Loan Agreement accrued interest at a floating per annum rate equal to the greater of (i) 7.30% or (ii) the sum of 7.30% plus the prime rate minus 5.75%. At the end of the loan term (whether at maturity, by prepayment in full or otherwise), Cerulean was required to pay a final end-of-term charge to Hercules in the amount of 6.7% of the aggregate original principal amount advanced by Hercules.

On March 17, 2017, Cerulean agreed with Hercules that Hercules would consent to the sale of assets to BlueLink, pursuant to the BlueLink Asset Purchase Agreement, and that Cerulean would repay Hercules in full. On March 20, 2017, Cerulean paid $12.4 million to Hercules, representing the principal, accrued and unpaid interest, fees, costs and expenses outstanding under the Hercules Loan Agreement in full repayment of its outstanding obligations under the Hercules Loan Agreement which was terminated. There were no prepayment charges associated with the early repayment of the loan.

Plan of Operations and Future Funding Requirements

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

Following the closing on July 19, 2017 of the Stock Purchase Transaction and the sale of our right, title and interest in and to the patent rights, know-how and third-party license agreements relating to the Platform to Novartis for $6 million, we believe that our existing resources will be sufficient to fund our planned operations for approximately two years. 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 our lead clinical candidate, Ovaprene® during this period. 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 need to raise additional financing to continue the clinical development of Ovaprene®, including a pivotal contraceptive study, and to support new licenses or other rights related to future portfolio candidates. We will seek to fund our operations through public or private equity, debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. We can make no assurances that we will be able to raise the cash needed to fund the development of Ovaprene®, potential other product candidates and our operating expenses.

Cash Flows

The following table sets forth the primary sources and uses of cash of Cerulean for each period set forth below (in thousands):

	Six Months Ended June 30,	
	2017	2016
Net cash used in operating activities	$ (15,416)	$ (24,501)
Net cash used in investing activities	2,124	(355)
Net cash (used in) provided by financing activities	(14,414)	(3,859)
Net (decrease) increase in cash and cash equivalents	$ (27,706)	$ (28,715)

Net Cash Used in Operating Activities

The net use of cash in each period resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

During the six months ended June 30, 2017, cash used in operating activities consisted of Cerulean's net loss of $10.5 million, net cash used in changes in operating assets and liabilities of $4.2 million and the non-cash adjustment for the gain on sale of asset of $1.5 million, partially offset by net non-cash charges of $0.8 million. Net non-cash charges during the period consisted primarily of stock-based compensation expense and amortization of debt discount and deferred financing costs offset by deferred revenue. Cash used in changes in operating assets and liabilities consisted of a decrease in accounts payable and accrued expenses of $5.2 million and partially offset by a decrease in accounts receivable and prepaid expenses of $1.0 million.

During the six months ended June 30, 2016, cash used in operating activities consisted of Cerulean's net loss of $24.4 million and net cash used in changes in operating assets and liabilities of $2.1 million, partially offset by non-cash charges of $2.0 million. Net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash used in changes in operating assets and liabilities consisted of a net decrease in accounts payable and accrued expenses of $1.7 million, and an increase in accounts receivable, prepaid expenses and other current assets of $0.3 million.

Net Cash Provided by (Used in) Investing Activities

During the six months ended June 30, 2017, net cash provided by investing activities of $2.1 million was attributable to proceeds of $1.5 million from the sale of assets under the BlueLink Asset Purchase Agreement, proceeds from the sale of lab equipment of $0.4 million, and $0.2 million from a decrease in restricted cash used to collateralize a stand-by letter of credit issued as a security deposit on our facility lease which was terminated in May 2017.

During the six months ended June 30, 2016, net cash used in investing activities was primarily attributable to purchases of property and equipment of $0.5 million partially offset by cash proceeds of $0.1 million from a decrease in restricted cash used to collateralize a stand-by letter of credit issued as a security deposit on our former facility lease.

Net Cash Used in Financing Activities

During the six months ended June 30, 2017, net cash used in financing activities was primarily attributable to principal payments of $13.1 million reflecting payment in full of the principal balance and $1.4 million for the end of term charge due under the Hercules Loan Agreement.

During the six months ended June 30, 2016, net cash used in financing activities was primarily attributable to principal payments of $3.9 million under the Hercules Loan Agreement.

Contractual Obligations and Contingent Liabilities

On May 31, 2017, Cerulean entered into a Lease Termination Agreement with its landlord to terminate its lease for office and laboratory space of the former headquarters at 35 Gatehouse Drive in Waltham, Massachusetts.

As of June 30, 2017, besides the Lease Termination Agreement, there were no material changes, outside of the ordinary course of business, in Cerulean's outstanding contractual obligations from those disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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.

Recent Accounting Pronouncements

Please refer to Note 2 to our consolidated financial statements included in Part I, Item 1, "Financial Statements (Unaudited)" of this quarterly report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2017, we had cash and cash equivalents of approximately $7.2 million, consisting primarily of investments in money market funds and certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in cash and cash equivalents. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosures.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2017.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

Our business faces significant risks and uncertainties. Our risks have changed in light of the Stock Purchase Transaction and sale of the Platform to Novartis. Certain important factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC.

Risks Related to Our Business

We expect to be heavily reliant on our ability to access funding 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.

We expect to be heavily reliant on our ability to raise funds through the issuance of shares of our common stock or securities linked to our common stock. Our ability to raise these funds may be dependent on a number of factors, including the risk factors further described below and the low trading volume and volatile trading price of our shares of common stock. The stocks of small cap companies in the biotechnology sector like ours tend to be highly volatile. We expect that the price of our common stock will be highly volatile for the next several years as we undertake studies and trials to obtain regulatory approval for our sole product candidate. Even if we expand our portfolio of products and product candidates, we may never successfully commercialize or monetize our current sole product candidate or any future product candidate that we may seek to develop.

As a result, we may be unable to access funding through sales of our common stock or other equity-linked securities. Even if we are able to access funding, the cost of capital may be substantial due to our low market cap and our small public float. The terms of any funding we are able to obtain may not be favorable to us and may be highly dilutive to our stockholders. We may be unable to access capital due to unfavorable market conditions or other market factors outside of our control. 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 our business.

We only have a limited number of employees to manage and operate our business. If we fail to attract and retain management and other key personnel, we may be unable to successfully commercialize our products, develop any product candidates or otherwise implement our business plan.

As of July 31, 2017, we had a total of three full-time employees and no employees working on a part-time basis. Our focus on limiting cash utilization requires us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

Our ability to compete in the highly competitive pharmaceutical and medical device industries depends upon our ability to attract and retain highly qualified managerial and key personnel. We are highly dependent on our senior management, including our President and Chief Executive Officer, Sabrina Martucci Johnson, and our Chief Financial Officer, Lisa Walters-Hoffert. The loss of the services of either of these individuals could impede, delay or prevent the development and commercialization of our product candidates, hurt our ability to raise additional funds and negatively impact our ability to implement our business plan. If we lose the services of either of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, medical device, pharmaceutical and other businesses, particularly in the San Diego area where we are headquartered. As a result, we may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other companies within the contraceptive industry with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

Our current or future employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We may become exposed to the risk of employees, independent contractors, principal investigators, consultants, suppliers, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could include intentional failures such as failures: (i) to comply with FDA or other regulators’ regulations, (ii) to provide accurate information to such regulators or (iii) to comply with manufacturing

standards established by us and/or required by law. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws, regulations and industry guidance intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by current or future employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory or civil sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant adverse impact on our business, including the imposition of significant fines or other sanctions, and our reputation.

We may be vulnerable to disruption, damage and financial obligations as a result of information technology system failures.

Despite the implementation of security measures, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failure. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For example, the loss of clinical study data from future clinical studies could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure, which could disrupt our operations. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability, our product development programs and competitive position may be adversely affected and the further development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

We have incurred significant losses since our inception and expect to continue to incur losses in the foreseeable future. We must raise additional funds to finance our operations and remain a going concern.

Since inception, we have incurred significant operating losses. Negative cash flows from our operations are expected to continue for the foreseeable future. Our utilization of cash has been and will continue to be highly dependent on our product development programs, particularly our programs for Ovaprene®. Our cash expenses will be highly dependent on the product development programs we choose to pursue, the progress of these product development programs, the results of our preclinical studies and clinical trials, the cost, timing and outcomes of regulatory decisions regarding potential approval for our product candidate or any future product candidate 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.

Our current cash reserves are expected to fund our planned operations for approximately two years. 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 continue the development of our current product candidate and any future product candidates. However, there can be no assurance that we will complete any financings, strategic alliances or collaborative development agreements, or that the terms of such financings, alliances or agreements would be advantageous to us. The fees associated with raising capital and the effective cost of such capital for small public companies like ours may be more expensive when compared to the cost of capital for larger public companies. If we are unable to raise additional funds when needed, we will not be able to continue development of our product candidate or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations. Any additional equity or convertible debt financing that we are able to obtain may be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants or unfavorable terms. If we raise funds through collaborative or licensing 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.

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 candidate, and we may be unable to pursue and complete the clinical trials that we would like to pursue and complete.

We have limited financial and technical resources to determine the indications on which we should focus the development efforts for our product candidate and any future candidates we may choose to develop. Due to our limited available financial 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 continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we will be incurring and expect to continue to incur additional significant legal, accounting and other expenses in relation to our status as a public reporting company. We expect that these expenses will further increase after we are no longer an "emerging growth company." We expect that we will need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), we will be required to furnish a report by our management on our internal controls over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, this could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Risks Related to Clinical Development, Manufacturing and Commercialization

Our success will depend heavily on whether we can develop our sole product candidate, Ovaprene®. Failure to develop Ovaprene® would likely cause our business to fail. Should we fail to expand our portfolio, our license to Ovaprene® would be our only asset.

We currently have only one product candidate, Ovaprene®, and our business depends almost entirely on the successful clinical development and regulatory approval of this candidate, which may never occur. Ovaprene® will require substantial clinical testing in order to demonstrate that it is a safe and effective contraceptive option. We have never received a regulatory approval for any product. Accordingly, even if we are able to conduct clinical trials for Ovaprene®, we may be unable to successfully develop or obtain regulatory approval for Ovaprene®, which would have a material adverse effect on our business and operations. We are seeking to license the product and technology rights to a variety of products 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.

We are highly dependent on our license agreement with ADVA-Tec, Inc., and the loss or impairment of this license would have a materially adverse impact on our business prospects, operations and viability.

We signed a license agreement for the exclusive rights to develop and commercialize Ovaprene® worldwide from ADVA-Tec. As Ovaprene® is currently our only product candidate, our license agreement with ADVA-Tec is critical to our business. If our license agreement with ADVA-Tec is otherwise terminated, impaired, or limited, we could lose the ability to develop and commercialize Ovaprene®, which would have a materially adverse impact on our business prospects, operations and viability. In addition to standard termination rights, the license agreement permits ADVA-Tec to terminate the license agreement if we (i) fail to make significant scheduled investments in product development activities over the course of the agreement, (ii) fail to commercialize Ovaprene® within six (6) months of PMA from the FDA, (iii) with respect to the license in any particular country, fail to commercialize Ovaprene® in that particular country within three (3) years of the first commercial sale, (iv) develop or commercialize a non-hormonal ring-based vaginal contraceptive device other than Ovaprene® or (v) fail to conduct certain clinical trials.

Ovaprene®, is a drug/device combination and the process for obtaining regulatory approval for Ovaprene® in the United States will require compliance with requirements of two agencies of the FDA. A change in the FDA's primary oversight responsibility would adversely impact our development timeline and significantly raise our costs.

Ovaprene® is comprised of both device and drug components and is considered a combination product by the FDA. It has a contraceptive intravaginal ring design that includes a permeable mesh in the center of the ring that creates a partial barrier to sperm, and a release through the ring of locally acting spermiostatic agents. The barrier seeks to block the progression of sperm into the cervical mucus while the agents seek to create an environment that is inhospitable to sperm. The FDA has different divisions responsible for assessing and approving devices and drugs. CDRH has oversight responsibility for medical devices, while Center for Drug Evaluation and Research ("CDER") has responsibility for drug products. Ovaprene® previously underwent a request for designation process with the FDA that determined that CDRH would lead the review. If the designation were to be changed to CDER, or if either division were to institute additional requirements for the approval of Ovaprene®, we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would require us to raise additional funds and would cause us to miss anticipated timelines. Because Ovaprene® is our only product candidate currently in development, the impact of either a change in review agency or the imposition of additional requirements for approval would be significant to us and would have a material adverse effect on the prospects for the development of Ovaprene®, our business and our financial condition.

Our product candidate, Ovaprene®, and any future product candidate we may seek to develop, may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require it to be taken off the market, require it to include safety warnings or otherwise limit our sales.

Serious adverse events or undesirable side effects from Ovaprene®, or any other future product candidate we may seek to develop, could arise either during clinical development or, if approved, after approval and commercialization. The results of future clinical studies may show that Ovaprene®, or a future product candidate that we seek to develop, causes serious adverse events or undesirable side effects, which could interrupt, delay, or cause the termination of clinical studies, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If such serious adverse events or undesirable side effects occur:

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of specific warnings or contraindications to product labeling or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered or the labeling of the product;
- we may be required to conduct additional clinical studies with more patients or over longer periods of time than anticipated;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the patients who can receive the product;
- we may be subject to promotional and marketing limitations on the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take an approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Ovaprene® or any future product candidate we may seek to develop, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from Ovaprene® sales or the sales from any future product candidate.

If we fail to enter into strategic relationships or collaborations, our business, financial condition, commercialization prospects and results of operation may be materially adversely affected.

Our expected strategy with respect to the development and potential commercialization of Ovaprene®, and any future product candidates, is to supplement internal efforts with third-party collaborations. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming arrangements to negotiate and document.

Our success in entering into a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design and outcomes of the clinical studies, the likelihood of

approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such products to customers, the potential of competing products, the strength of the intellectual property and industry and market conditions generally. The collaborator may also consider alternative products or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our products or product candidates.

Any potential collaboration agreement into which we might enter may call for licensing or cross-licensing of potentially blocking patents, know-how or other intellectual property. Due to the potential overlap of data, know-how and intellectual property rights, there can be no assurance that one of our collaborators will not dispute its right to use, license or distribute such data, know-how or other intellectual property rights, and this may potentially lead to disputes, liability or termination of the collaboration.

We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators and may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product, reduce or delay our development program, delay commercialization, reduce the scope of sales or marketing activities, or increase expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. Absent sufficient funds, we may not be able to commercialize a product candidate. If we enter into a collaboration agreement regarding a product or product candidate, we could be subject to, among other things, the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the product development program;
- we may experience financial difficulties and thus not commit sufficient financial resources to the product development program;
- we may be required to relinquish important rights to the collaborator such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- a collaborator could terminate the agreement (for convenience if permitted) or for our breach; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

Contraception is a highly competitive healthcare niche. The success of Ovaprene® and any other future contraceptive product candidate we may pursue will be related to its efficacy and safety outcomes during clinical trials.

Today, there are a variety of hormonal and non-hormonal contraceptive options available to women and men, 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, easy-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) approaching that of a diaphragm which is approximately 88%. 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.

The proportion of the contraceptive market that is made up of generic products continues to increase, making introduction of a branded contraceptive difficult and expensive.

The proportion of the U.S. market that is made up of generic products has been increasing over time. In 2005, generic contraceptive products held 47% of prescription volume and 34% of sales and, by 2011, those values had risen to 68% and 44%, respectively. For the year ended December 31, 2016, approximately 83% of the prescription volume and approximately 43% of sales of combined hormonal contraceptives in the United States were generated by generic products. If this trend continues, it may be more difficult to introduce Ovaprene®, if approved, or any future approved contraceptive product candidate we may develop, as a branded contraceptive, at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to introduce Ovaprene® in order to overcome the trend towards generics and to gain access to reimbursement by payors. If we are unable to introduce Ovaprene® or any future approved contraceptive product candidate at a price that is commensurate with that of current branded contraceptive products, or we are unable to gain reimbursement from payors for Ovaprene®, or if patients are unwilling to pay any price differential between Ovaprene® and a generic contraceptive, our revenues will be limited.

Changes in healthcare laws and regulations may eliminate current requirements that health insurance plans cover and reimburse FDA-cleared or approved contraceptive products without cost sharing, which could reduce demand for products such as Ovaprene®. Even if Ovaprene® is approved for commercialization, we expect that our success will be dependent on the willingness or ability of patients to pay out-of-pocket should they not be able to obtain third party reimbursement or should such reimbursement be limited.

We cannot be certain that third party reimbursement will be available for Ovaprene®, and if reimbursement is available, the amount of any such reimbursement. The Patient Protection and Affordable Care Act of 2010 (the "PPACA") and subsequent regulations enacted by the Department of Health and Human Services ("DHHS"), require health plans to provide coverage for women's preventive care, including all forms of FDA-cleared or approved contraception, without imposing any cost sharing on the plan beneficiary. These regulations ensure that women who wish to use an approved form of contraception may request it from their doctors and their health insurance plan must cover all costs associated with such products. However, after the 2016 election, the U.S. Federal Government is attempting to repeal the PPACA and corresponding regulations, which would likely eliminate the requirement for health plans to cover women's preventive care without cost sharing. Even if the PPACA is not repealed, the DHHS regulations to specifically enforce the preventive health coverage mandate could be repealed under the Congressional Review Act. Any repeal or elimination of the preventive care coverage rules would mean that women seeking to use prescribed forms of contraceptives may have to pay some portion of the cost for such products out-of-pocket, which could deter some women from using prescription contraceptive products, such as Ovaprene®, at all. As a result, we expect that our success will be dependent on the willingness of patients to pay out-of-pocket for Ovaprene® in the event that either they do not have insurance or their insurance requires payment of a portion of Ovaprene® by the patient, thus increasing the patient's overall cost to use Ovaprene®. This could reduce market demand for Ovaprene® or any future product candidates we may seek to develop, if and when they receive FDA approval, which would have a material adverse effect on our business, financial conditions, and prospects.

In the event that we are successful in obtaining regulatory approval to market Ovaprene® or a future product in the United States, revenues may be adversely affected if the product fails to obtain insurance coverage or adequate reimbursement from third-party payers and administrators in the United States.

Third-party payers and administrators, including state Medicaid programs and Medicare, have recently been challenging the prices charged for pharmaceutical and medical device products. The United States government and other third-party payers are increasingly limiting both coverage and the level of reimbursement for new drugs and medical devices. Third-party insurance coverage may not be available to patients for Ovaprene® or any future product we may seek to commercialize. If such government and other third-party payers do not provide adequate coverage and reimbursement for Ovaprene® or such products, healthcare providers may not prescribe them or patients may ask their healthcare providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Private third-party payers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Ovaprene® or any future product we may seek to commercialize, or obtaining such pricing or placement at unfavorable pricing levels, could materially adversely affect our business, financial conditions, results of operation and prospects.

The pharmaceutical and medical device industries are highly regulated and subject to 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.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, among other things:

- the federal healthcare programs' anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Regulatory authorities might challenge our current or

future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws will involve substantial costs. Any investigation of us or the third parties with whom we contract, regardless of the outcome, would be costly and time consuming.

Delays in the commencement or completion of clinical testing of Ovaprene® and any other future product candidate we may seek to develop could result in increased costs, longer timelines and impact our ability to ever become profitable. Clinical testing is time consuming and expense and their outcome is uncertain.

We intend to commence a postcoital test clinical trial during the second half of 2017 in order to assess the safety and preliminary efficacy of Ovaprene®. The actual commencement and completion of this study and other clinical trials may vary dramatically due to factors within and outside of our control, and the results from early clinical studies may not necessarily be predictive of results obtained in later clinical studies; even if results from early clinical studies are positive, we may not be able to confirm those results in future clinical studies. Further, clinical studies may not ever demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates. Any change in, or termination of, clinical studies could materially harm our business, financial condition, and results of operations.

The tests and clinical trials for Ovaprene®, and any future product candidate we may seek to develop may not commence, progress or be completed as expected, and delays would significantly impact our product development costs and timelines. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining required funding;
- Slower than expected rates of recruitment and enrollment;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining sufficient quantities of clinical trial materials for product candidates;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- recruiting participants in a timely manner.

In addition, once a clinical trial has begun, it may experience unanticipated delays or be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, all of which could impact our ability to complete our trials in a timely and cost-efficient manner, including:

- failure to conduct the clinical trial in accordance with regulatory requirements;
- higher than anticipated participant drop-out rates;
- failure of clinical trial participants to use the product as directed or to report data as per trial protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- failure to achieve certain efficacy and/or safety standards; or
- lack of adequate funding to continue the clinical trial.

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 Ovaprene® and potential future product candidates.

We have a very small number of employees and no marketing, manufacturing or sales and distribution departments. We do not expect to manufacture any products and expect to rely on third parties to make our 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.

Moreover, we do not expect to control the manufacturing processes for the production of Ovaprene® or any of our other future products or product candidates, 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, all of which would result in suspension or prevention of commercialization and/or manufacturing of our products or product candidates, including Ovaprene®, 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, including the distribution of Ovaprene® or any future product candidate or product, 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 and the maintenance of records and documentation. 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 it fails to maintain relationships with its current suppliers, manufacturers, distributors or regulatory service providers, including ADVA-Tec, we may not be able to complete development of Ovaprene® or any other future product candidates, or to commercialize or market any products following approval, including Ovaprene®, 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, if one is available.

Additionally, any failure by us to forecast demand for finished product, including Ovaprene®, 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 studies 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.

We intend to rely on third-parties for the execution of certain of our development programs for Ovaprene® and our potential future product candidates. Failure of these third parties to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of our development programs.

We intend to employ a business model that relies on the outsourcing of certain functions, tests and services to CROs, medical institutions and other specialist providers. We will rely on these third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. In terms of Ovaprene®, we have identified a CRO to run all aspects of the postcoital test clinical trial expected to commence in the second half of 2017. We also intend to engage a CRO for all future clinical trial requirements needed to file for regulatory approvals. There is no assurance that such organizations or individuals will be able to provide the functions, tests or services as agreed upon, or to the requisite quality. We will rely on the efforts of these organizations and individuals and could suffer significant delays in the development of its product or processes should they fail to perform as expected.

There is also no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, regulatory approval of Ovaprene®, or any future product candidates, may be delayed, prevented or cost significantly more than expected, all of which would have a material adverse effect on our business, financial conditions, results of operation and prospects.

The commercial success of Ovaprene® and any future product candidates will depend in significant measure on the label claims that the FDA or other regulatory authorities approve for the product.

The commercial success of Ovaprene® and any of our future product candidates will depend in significant measure upon our ability to obtain approval from the FDA or other regulatory authorities of labeling describing a product candidate’s expected features or benefits. Failure to achieve approval from the FDA or other regulatory authorities of product labeling containing adequate information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate Ovaprene® or any future product candidate from those products that already exist in the market. This failure would have a material adverse impact on our business, financial condition, results of operation and prospects.

Even if we receive approval from the FDA in the United States to market Ovaprene® or a future product candidate we may seek to develop, it may fail to receive similar approval outside the United States.

In order to market a new product outside the United States, we must obtain separate marketing approvals in each jurisdiction and comply with numerous and varying regulatory requirements of other countries, including clinical trials, commercial sales, pricing manufacture distribution and safety requirements. The time required to obtain approval in other countries might differ from, and be longer than, that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the United States, as well as other risks. Further, we may be unable to obtain rights to the necessary clinical data and may be required to develop our own. In addition, in many countries outside the United States, a new product must receive pricing and reimbursement approval prior to commercialization. This can result in substantial delays in these countries. Additionally, the product labeling requirements outside the United States may be different and inconsistent with the United States labeling requirements, negatively affecting the ability of us to market our products in countries outside the United States.

In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if it fails to comply with applicable foreign regulatory requirements. In such an event, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidate will be harmed, which could have a materially adverse effect on our business, financial condition, results of operation and prospects.

Our sole product candidate, Ovaprene®, and any of our future potential product candidates, may not gain acceptance among physicians, patients or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.

Even if Ovaprene® or any of our future product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any new product by physicians, health care professionals and third-party payors will depend on a number of factors, including:

- demonstrated evidence of efficacy and safety;
- sufficient third-party insurance coverage or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- the willingness of uninsured consumers to pay for the product;
- the willingness of pharmacy chains to stock the products;
- the prevalence and severity of any adverse side effects; and
- availability of alternative products.

If Ovaprene® or any product candidate that we may license, develop or sell does not provide a benefit over currently available options, that product is unlikely to achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

The success of Ovaprene®, or any future contraceptive product candidate we may seek to develop, will depend on the availability of contraceptive alternatives and women's preferences, in addition to the market's acceptance of this specific method of contraception.

The commercial success of Ovaprene®, or any other future contraceptive product candidate we may seek to develop, will depend upon the contraceptive market as well as market acceptance of this alternative method. Risks related to market acceptance include, among other things:

- minimum acceptable contraceptive efficacy rates;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options ;
- changes in healthcare laws and regulations, including the PPCA, and its effect on pharmaceutical coverage, reimbursement and pricing, and the birth control mandate;
- competition from new lower dose hormonal contraceptives with more favorable side effect profiles; and
- new generic contraceptive options including a generic version of NuvaRing®.

If one or more of these risks occur it could reduce the market potential for Ovaprene®, or any future contraceptive product we may seek to develop, and place pressure on our business, financial condition, results of operation and prospects.

If we suffer negative publicity concerning the safety or efficacy of our products in development, our reputation could be harmed and we may be forced to cease development of such products.

If concerns should arise about the actual or anticipated clinical outcomes regarding the safety of any of our product candidates, such concerns could adversely affect the market's perception of these candidates. Such concerns could lead to a decline in investors' expectations and a decline in the price of our common stock.

We face competition from other medical device, biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The medical device, biotechnology and pharmaceutical industries are intensely competitive. Significant competition among various contraceptive products already exists. Existing products have name recognition, are marketed by companies with established commercial infrastructures and with greater financial, technical and personnel resources than us. In order to compete and gain market share, any new product will need to demonstrate advantages in efficacy, convenience, tolerability or safety. In addition, new products developed by others could emerge as competitors to Ovaprene®, if approved. Such products could offer an alternative form of non-hormonal contraceptive that provides protection over longer periods of time. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors include large, well-established pharmaceutical companies and specialty pharmaceutical companies. These companies include Merck & Co., Inc., Agile Therapeutics, Inc., Allergan, Inc., Teva Pharmaceutical Industries Ltd., Bayer AG, Johnson & Johnson, Pfizer Inc. and Mylan Inc. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc. and Amneal. Pharmaceuticals LLC. There are other contraceptive product candidates in development that, if approved, would potentially compete with Ovaprene®, including hormonal patches and hormonal vaginal rings.

Our business may be adversely affected by unfavorable macroeconomic conditions.

Various macroeconomic factors could adversely affect our business, our results of operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty) and the current and future conditions in the global financial markets. For example, if inflation or other factors were to significantly increase our business costs, it may be unable to pass through price increases to patients. The cost of importing similar products from foreign markets may affect our sales in any domestic market.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payers and distributors to purchase, pay for and effectively distribute our product if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future third-party manufacturers, sole source or single source suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply our product candidate. Failure by any of them to remain in business could affect our ability to manufacture Ovaprene® or any of our future product candidates.

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 our Ovaprene® product candidate 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.

There is a substantial backlog of patent applications at the United States Patent and Trademark Office ("USPTO"). 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 license from ADVA-Tec for our Ovaprene® product candidate. 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 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.

We may become involved in patent litigations 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®.

Our exclusive, in-license agreement covering the critical patents and related intellectual property related to Ovaprene® imposes significant monetary obligations and other requirements that may adversely affect our ability to execute our business plan. The termination of this in-license agreement would prevent us from commercializing Ovaprene®.

Our license agreement with ADVA-Tec includes intellectual property rights to Ovaprene®. This agreement requires 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 this in-license agreement 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 this proprietary technology, which would have a material adverse effect on our business, financial condition and results of operations.

Further, there is no assurance that the existing ADVA-Tec license agreement covering the rights related to Ovaprene® will not be terminated due to a material breach of the underlying agreement. This would include a failure on our part to make the 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. There is no assurance that we will be able to renew or renegotiate a license agreement on acceptable terms if the agreement is terminated. We cannot guarantee that any license agreement will be enforceable. The termination of this license agreement or our inability to enforce our rights under this license agreement would materially and adversely affect our ability to commercialize Ovaprene®.

Risks Related to Our Common Stock

The price of our common stock may be volatile.

The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the results of our efforts to discover, develop, acquire or in-license product candidates or products, if any;
- failure or discontinuation of any of our research programs;
- actual or anticipated results from, and any delays in, any future clinical trials, as well as results of regulatory reviews relating to the approval of any product candidates we may choose to develop;
- the level of expenses related to any product candidates that we may choose to develop or clinical development programs we may choose to pursue;
- commencement or termination of any collaboration or licensing arrangement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in companies’ stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business and financial condition.

Our executive officers and directors and their affiliates will own a significant percentage of our issued and outstanding common stock and are able to exercise significant influence over matters submitted to stockholders for approval.

Our executive officers and directors and their affiliates beneficially own approximately 42% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to exert a significant degree of influence over

matters submitted to our stockholders for approval, as well as our management and affairs. This concentration of voting power could delay or prevent an acquisition on terms that other stockholders may desire. For example, these persons, if they choose to act together, would be able to have significant influence on the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

A significant portion of our total outstanding shares of common stock may be sold into the public market at any point, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

As of July 31, 2017, there were 554,259 shares of the Company subject to outstanding options. 544,110 of these shares under the Securities Act have been registered on a registration statement on Form S-8. These shares can be freely sold in the public market upon exercise, except to the extent they will be held by our affiliates, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Furthermore, as of July 31, 2017, there were 30,503 shares subject to outstanding warrants to purchase common stock. These shares will become eligible for sale in the public market, to the extent such warrants are exercised, as permitted by Rule 144 under the Securities Act. Moreover, holders of approximately 6.3 million shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements we may file on behalf of the Company or other stockholders.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "***JOBS Act***"), and may remain an emerging growth company through 2019. For so long as we remain an emerging growth company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of its internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock price may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to utilize this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our common stock.

We have never declared or paid cash dividends on shares of our capital stock. We currently plan to retain all of our future earnings, if any, and any cash received as a result of the Novartis Transaction to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders for the foreseeable future.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of the Company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our certificate of incorporation, our bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions might frustrate or prevent any attempts by our stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of directors to be changed only by resolution of the board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize the board to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board; and
- require the approval of the holders of at least 75% of the votes that all stockholders would be entitled to cast to amend or repeal certain provisions of the charter or bylaws.

In addition, we are governed by Section 203 of the DGCL, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of its voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our common stock could decline. In addition, if one or more of these analysts cease coverage or fail to regularly publish reports on our business, we could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.

Item 5. Other Information.

BUSINESS

Company Overview

Daré is a healthcare company committed to the development and commercialization of innovative products in women's reproductive health. We believe there is an unmet need in the United States and other developed and developing countries for innovative reproductive healthcare products that expand options, improve outcomes and are easy to use. We believe this is particularly true in the case of contraception. Approximately 62% of women of reproductive age in the United States currently use contraception, and 22% of those women use a non-hormonal method of contraception *(Guttmacher Institute)*. Approximately 64% of married and cohabiting women worldwide use some form of contraception *(UN Department of Economic and Social Affairs)*. However, as many as 40% of women using contraception say they are not satisfied with their current method, reporting difficulty of use, problems with side effects, and concerns about effectiveness and reduced sexual pleasure (*Ersek, J, Matern Child Health J (2011) 15:497–506)*.

While there are many factors impacting a woman's contraceptive preference, Daré believes that a convenient, easy-to-use and effective non-hormonal option could have broad appeal to the 22% of women currently using a non-hormonal method and may also help address the needs of the nearly 40% of women dissatisfied with their current method of contraception. Further, the Guttmacher Institute reported that in 2016 there was an estimated 225 million women in developing regions wishing to avoid pregnancy but not using any form of contraception. Many women would benefit from the availability of new and improved contraceptive options that better suit their specific needs.

Short-acting, easily reversible contraceptive methods are used by about half of women using some form of birth control today (*Guttmacher Institute*). While a variety of hormonal and non-hormonal short-acting options exist, there is one notable void: a short-acting, non-hormonal method that does not require intervention at the time of intercourse. This is the void that we seek to fill by developing Ovaprene®. Ovaprene® is a non-hormonal contraceptive intravaginal ring intended to provide protection over multiple weeks of use and that requires no intervention at the time of intercourse. If approved, Ovaprene® would represent a new category of birth control.

Daré's business strategy is to license the rights to novel reproductive health product candidates, some of which have existing clinical proof-of-concept data, and to take those candidates through advanced stages of clinical development. We believe that there is an opportunity to fill the gap in the clinical development of women's healthcare products between (a) non-profit organizations and small private companies that discover, innovate and conduct early clinical development of product candidates, and (b) large pharmaceutical companies that conduct late-stage clinical development and commercialize approved products. Daré believes that the two ends of the development spectrum are being adequately addressed but that the stages of clinical development between early clinical development of product candidates and commercialization of product candidates by large pharmaceutical companies are underserved. Daré intends to fill this gap. The dynamics of the contraceptive market in particular provide an opportunity for us to assemble a portfolio of candidates, including clinical-stage candidates, often with published human data. Daré believes it can enter into agreements that will allow it to advance the clinical development of these candidates and, if successful, create a comprehensive global commercialization strategy in combination with established pharmaceutical partners and regional distributors.

Product Candidate - *Ovaprene®*

Daré selected Ovaprene® as its first product candidate because it has the potential to address two unmet needs: (1) improved convenience as compared with other short-acting non-hormonal methods and (2) effectiveness in the range of diaphragms and short-acting hormonal methods. Specifically, Ovaprene® could provide multiple weeks of contraceptive protection without the use of hormones. Ovaprene® has a custom intravaginal ring design, with a permeable mesh in the center of a small silicone ring that creates a partial barrier to sperm, and a mechanism to release locally acting spermiostatic agents through the ring. The silicone ring releases ingredients designated by the FDA as generally regarded as safe (GRAS)—ascorbic acid and ferrous gluconate—which act together to create a spermiostatic environment through pH buffering and the immobilization of sperm. The non-braided multi-filament mesh component functions as a physical barrier to sperm. The unique combination of these two complementary approaches seeks to produce attractive contraceptive efficacy outcomes that are consistent with the most effective barrier option, the diaphragm, and short-acting hormonal options (pill, patches and vaginal ring) that provide 88-91% effectiveness in typical use (typical use refers to effectiveness experienced among all couples who use the method, including inconsistent and incorrect use).

In a PCT clinical trial conducted in 21 women and published in the Journal of Reproductive Medicine in 2009, Ovaprene® demonstrated the ability to immobilize sperm and prevent their progression into the cervical mucus. The pilot study also demonstrated the acceptability of the device to both partners. No serious adverse events were reported during this study (Journal of Reproductive Medicine 2009; 54:685–690). While the study was not designed to be utilized as part of a regulatory submission, this PCT provides proof-of-concept of contraceptive efficacy. The PCT was originally developed to assess infertility in couples, and has since evolved into the industry standard test of initial contraceptive efficacy for vaginal chemical (spermicide) and barrier devices. The PCT is

performed near the time of ovulation and within hours of intercourse. Cervical mucus is isolated and analyzed for the quantity and quality of motile sperm. The quantity and quality of motile sperm able to reach the cervical mucus serve as a proxy for determining potential, or preliminary, contraceptive efficacy. Contraceptive success is demonstrated by the prevention of viable sperm from reaching the cervical mucus. In three studies of similar size conducted with three other products, those products that, like Ovaprene®, had no motile sperm in the cervical mucus in their PCT assessments demonstrated typical use contraceptive effectiveness of 88% in pivotal clinical trials evaluating pregnancy rates over time.

Daré plans to conduct a PCT clinical trial in approximately 15-30 women. Assuming a successful outcome, we intend to commence a pivotal clinical trial to support marketing approvals of Ovaprene® in the United States, Europe and other countries worldwide.

The Contraceptive Market

The global market for contraception was over $19 billion in 2015, and is estimated to grow over 6% from 2016 to 2023 to $33 billion according to a research report by Global Market Insights, Inc. released in February of 2017.

Current contraception options include both long-acting and short-acting contraceptives, and within these categories are hormonal and non-hormonal options. There is no single form of contraceptive protection that meets the varied needs of all women. In fact, a woman's preference may change multiple times during the course of her reproductive life based on her circumstances and health status. Hence, development efforts for new contraceptive methods must seek to expand the array of choices to address the differing needs and preferences of as many women as possible.

There are two categories of contraceptives:

Long-acting:

- Tubal ligation and fallopian tube inserts (permanent sterilization)
- Copper and hormonal intrauterine devices (3-10 years)
- Hormonal implants (3 years)

Short-acting:

- Non-hormonal condoms, diaphragms, caps, and spermicides used at the time of intercourse
- Hormonal pills taken daily; hormonal patch worn weekly; intravaginal hormonal ring used monthly

The attractiveness of long-acting options is that they provide contraceptive protection for multiple years with no intervention on the part of the woman. Intrauterine devices and hormonal implants require a health care provider to both place and remove the device. Because these devices remain in the body and there is no intervention required, these methods have the highest level of contraceptive effectiveness. The attractiveness of short-acting options is that they provide contraceptive protection, but are woman-initiated (so the woman herself can start or stop using the method on demand) and are therefore quickly reversible (www.fda.gov/birthcontrol). In the United States alone, approximately 40 million women are using some form of contraception, and about half of them are using a short-acting, reversible method.

Hormone-based contraceptives remain the most widely embraced short-acting option because of their high rates of typical use effectiveness. However, many women do not tolerate hormones well and experience breast tenderness, bloating, mood swings or other side effects. In other cases, the use of hormone-based contraceptives is contraindicated given health issues. A high body mass index can reduce the effectiveness of hormonal contraception. Some women want to take a break from hormone-based contraceptives. Pill users may find taking a pill every day to be inconvenient, which makes compliance difficult. And, some women simply do not want to take hormone-based contraceptives for several years and therefore seek alternative forms of birth control.

The unmet need

A gap exists in today's method mix—there is need for a safe non-hormonal contraceptive method that does not require action at the time of intercourse but yet, like diaphragms, provides a level of contraception typical use effectiveness approaching that of hormones. Today's most popular short-acting non-hormonal contraceptive options include condoms and spermicides. All of these methods lack convenience as they must be used at the time of intercourse. Most have modest typical use efficacy. Typical use effectiveness of these most commonly used non-hormonal methods range from 72-82%.

Daré believes that a non-hormonal monthly contraceptive ring that is convenient (inserted and worn for multiple weeks), safe and demonstrates typical use effectiveness comparable to diaphragms, pills, patches and hormonal rings (which have 88-91% contraceptive effectiveness in typical use) has the potential to capture market share across the broad spectrum of short-acting methods,

primarily from non-hormonal contraceptive users and current non-users of any form of contraception, but also from a small segment of hormonal contraceptive users.

Three notable trends in contraceptive innovation.

- Since the introduction of the birth control pill in the United States in 1960, most advances in contraception have focused on the use of hormones. These include new contraceptive methods using existing hormones and new hormone combinations, lower doses of hormones, and different modes of hormonal delivery.
- Much of the transformational work in women's reproductive health has occurred at non-profit organizations or small private companies. In fact, 90% of the funding invested to expand options and choices for women comes from the global donor community of foundations, governments and philanthropists, including the Bill & Melinda Gates Foundation.
- The lack of commitment by established pharmaceutical companies with women's healthcare franchises to fund research and development has created a gap between early innovation and ultimate commercialization.

Daré believes that product development in women's health is characterized by adequate investment in early-stage research and development and late-stage development and commercialization, but inadequate investment in mid-stage development. On the one end of the development spectrum, thanks to the efforts of non-profit developers and private company innovators, innovative product candidates exist with proof-of-concept human data, many of which have been funded through the early high-risk phase of product development. On the other end of the development spectrum, established pharmaceutical companies are prepared to take late stage candidates through final clinical development and commercialization. However, there is a gap between these two endpoints, and Daré believes this gap creates a business opportunity.

Competition

Since the early 1960s when oral contraceptive pills and intrauterine devices were first introduced in the United States, many new hormonal contraceptive products have become available including implants, injectables, vaginal rings, patches, and hormonal intrauterine systems, as well as non-hormonal methods such as female condoms, novel diaphragms, and new methods of female sterilization. Numerous examples exist of successful commercial contraceptive brands including the hormonal vaginal ring, NuvaRing®, from Merck ($777 million in revenue in 2016) and the hormonal intrauterine system, Mirena®, a family of products from Bayer ($1.13 billion in revenues in 2016). Despite the numerous product advances over many years, the current available contraceptive method mix still fails to meet the needs of all women.

Market research has shown that most women would prefer a contraceptive method they don't need to remember to take every day and that does not require action at the time of intercourse:

- An estimated 67% of women said that a monthly vaginal ring has most of the features they deemed extremely important (Lessard, L, Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012).
- 85% would prefer a monthly option with a lower hormone dose than the oral birth control pill (Hooper, DJ, Clin Drug Investig. 2010;30(11):74963).
- An estimated 80% of women currently use a non-coital dependent method (Ersek, J, Matern Child Health J (2011) 15:497–506).

Daré believes that there is a need to improve the convenience of short-acting, non-hormonal methods, such that intervention is not required at the time of intercourse. There is also a need to improve the contraceptive effectiveness of non-hormonal methods so that they approach the same effectiveness level as short acting hormonal methods in typical use (such as the pill, patch, or vaginal ring). "Typical use" refers to effectiveness experienced among all couples who use the method, including inconsistent and incorrect use, as compared with "perfect use" which denotes effectiveness among couples who use the method both consistently and correctly. Thus, while the perfect use effectiveness of short-acting hormonal methods, such as oral contraceptives, is 99%, typical use effectiveness is lower, at 91%. The most commonly used non-hormonal method, the condom, has typical use effectiveness of only 82%. Diaphragms have typical use effectiveness of 88%, in the same range as short acting hormonal methods, but are not widely used due to the lack of convenience. Therefore, we believe that a short-acting, non-hormonal method with typical use effectiveness of 88%-91% would be an attractive new option for women.

Regulatory Matters

Ovaprene® previously underwent a request for designation ("RFD") process within the Office of Combination Products at the FDA. The FDA determined that Ovaprene® is a combination product, and the FDA designated Center for Devices and Radiological Health ("CDRH") as the lead agency FDA program center for premarket review because CDRH regulates devices that present similar safety and effectiveness questions with regard to a combination product, such as Ovaprene®, as a whole. In the RFD, the FDA

provided notice that CDRH has determined that a premarket approval application ("PMA") will be required. Any clinical investigations are subject to the investigational device exemption ("IDE") requirements found in 21 CFR 812.

An IDE has not yet been submitted for Ovaprene®. The planned PCT clinical trial will be conducted in advance of an IDE as a nonsignificant risk ("NSR") device study, since all participants in this study will have previously undergone permanent sterilization, so there is no risk of pregnancy. An NSR device study is one that does not meet the definition of the Significant Risk device study. Under 21 CFR 812.3(m), a Significant Risk ("SR") device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Sponsors are responsible for making the initial risk determination and presenting it to the Institutional Review Board ("IRB"). The IRB must review the sponsor's SR or NSR determination for every investigational medical device study reviewed and modify the determination if the IRB disagrees with the sponsor.

The pilot clinical study was conducted as an NSR device study in 21 women using Ovaprene® prior to Daré's involvement and published in the Journal of Reproductive Medicine in 2009. The pilot study was not designed to be utilized as part of a regulatory submission. Accordingly, we plan to initiate a PCT clinical trial commencing during the second half of 2017 in approximately 15-30 women. Daré intends to present this new study to an IRB as a NSR device study, consistent with the already completed and published prior PCT.

If there is demonstration of feasibility in the PCT clinical trial, we intend to prepare and file an IDE with the FDA to commence a pivotal clinical trial to support marketing approvals of Ovaprene® in the United States, Europe and other countries worldwide. Daré has not had communication with the FDA regarding the specific PMA requirements for Ovaprene®. However, given that the FDA has designated CDRH as the lead agency center for premarket review because CDRH regulates other devices that present similar safety and effectiveness questions with regard to a combination product, such as Ovaprene®, we believe the pivotal clinical trial will likely be similar to that of the most recent locally acting vaginal contraceptive devices cleared by CDRH. Additionally, Daré plans to communicate with the FDA regularly through pre-IDE and pre-submission meetings and intend to discuss alternative device regulatory pathways and classification with the FDA, as warranted, based on data developed in the PCT clinical trial.

Ovaprene® Clinical Development Plan

Daré has established relationships with, and intends to work closely with, both non-profit and for-profit developers who have clinical and regulatory expertise in reproductive health and have a proven track record of FDA success. Non-profit developers, such as Population Council and Medicines360, were responsible for the clinical development of some of today's popular contraceptive brands, and Daré believes working with an experienced development partner will provide for the efficient use of capital and time to advance Ovaprene® and any other future product candidates. We intend to conduct the PCT clinical trial of Ovaprene® with CONRAD, a non-profit organization established to improve reproductive health globally under a cooperative agreement between Eastern Virginia Medical School and the U. S. Agency for International Development (USAID). CONRAD oversaw the successful recent development and FDA approval of the Caya® diaphragm, the most recently approved barrier contraceptive device in combination with a locally-acting spermiostatic agent.

There are benefits of working with non-profit researchers and developers. The donor community that funds research and development shares our commitment to expanding options and improving outcomes for women. Thus, there may be funding opportunities, such as grants, which are not dilutive to equity holders, as well as opportunities for Daré to work or partner with non-profit organizations on development and distribution efforts to ensure the innovations reach women worldwide.

Unlike many therapeutic areas whose trial endpoints may be impacted by subjectivity or ambiguity, the clinical endpoints in contraceptive trials are straightforward and based on pregnancy outcomes.

Daré's anticipated clinical development timeline in the United States takes into account that the FDA previously determined that CDRH will be the lead reviewing agency for Ovaprene®, and that such review will be conducted in the interest of regulatory consistency, which we believe means in the context of other barrier contraceptive devices in combination with locally-acting spermiostatic agents. Daré believes those other product development plans leading to FDA approvals provide a good indication of the

FDA requirements likely to be required for Ovaprene®. Specifically, in addition to demonstrating biocompatibility and safety, we expect the clinical requirements for FDA approval for Ovaprene® to be:

- PCT Clinical Trial. Obtaining safety and preliminary efficacy data in 15-30 couples in a PCT clinical trial. Certain other commercially available barrier devices, including Lea's Shield, FemCap and the SILCS diaphragm (also known as Caya®) were initially evaluated in a PCT clinical trial prior to their pivotal clinical trials. The design of the planned PCT clinical trial of Ovaprene® will be guided by the size, structure and results of the PCT clinical trials associated with these other FDA approved devices. Daré intends to conduct the PCT clinical trial for Ovaprene® in collaboration with a leading organization in contraceptive research, CONRAD. CONRAD conducted the PCT clinical trials on numerous currently FDA approved barrier methods of contraception, and most recently conducted both the PCT and pivotal clinical trials for the Caya® diaphragm. The Caya® PCT clinical trial tested 15 women and required 14 months from start to finish, including recruitment (J.L. Schwartz et al. / Contraception 78 (2008) 237–244). Daré currently anticipates that the PCT clinical trial will be completed and results reported during the third quarter of 2019.
- Pivotal Clinical Trial. Conducting one large, single arm safety and contraceptive efficacy study, the pivotal clinical trial. The most recent contraceptive barrier device in combination with locally acting spermiostatic agents approved by CDRH is the Caya® diaphragm. The pivotal clinical trial for the Caya® diaphragm evaluated pregnancy rates in approximately 250 women over a period of six months. Assuming positive results from the planned PCT clinical trial, Dare's intention is to file the IDE with the FDA, proposing to conduct a similar pivotal contraceptive efficacy clinical trial for Ovaprene®. The Caya® pivotal clinical trial required 18 months from start to finish, including recruitment (Schwartz JL, Weiner DH, Lai JJ, et al. Contraceptive efficacy, safety, fit, and acceptability of SILCS, a novel single-size diaphragm. 2014). Daré anticipates that a similar timeline will be necessary to complete the Ovaprene® pivotal clinical trial. We expect to commence this single arm safety and contraceptive efficacy study in 2019, assuming completion of the PCT clinical trial as described above with satisfactory results and assuming we receive FDA clearance.
- PMA Filing. Assuming positive results from the Ovaprene® postcoital clinical trial over the next two years, followed by a successful outcome from the pivotal clinical trial, Daré anticipates filing the PMA during or prior to the fourth quarter of 2021.

The FDA's approval to commercialize a device based on a PMA submission is not based on a determination of substantial equivalence to any other product. However, as the Caya® diaphragm technology is similar to that of Ovaprene®, in that it was evaluated by CDRH as a barrier method in combination with spermiostatic agents, we intend to propose a similar clinical evaluation as that completed for Caya® – a PCT clinical trial feasibility study to demonstrate proof of concept, followed by a contraceptive effectiveness pivotal clinical trial, evaluating 250 subjects over the course of six months.

To meet the regulatory requirements of a PMA submission, the submission must contain completed nonclinical studies examining the safety, toxicology, microbiology, biocompatibility, shelf life, stress and wear of the product. From a clinical perspective, the submission must include safety and effectiveness data, adverse event reporting, patient information, patient complaints and patient use information. The PMA file must contain manufacturing information on the product that demonstrates it is manufactured using current Good Manufacturing Practices ("cGMP"), tested using Good Laboratory Practices ("GLP") and validated test methods to confirm it meets established specifications, and long-term stability data to demonstrate the product will remain stable and meet product specifications during its shelf life.

Foreign Regulations

Prior to the completion of the U.S. pivotal clinical trial of Ovaprene®, we may seek a CE Mark approval for Europe using a subset of the total pivotal clinical trial population based on an assessment by Novella/Quintiles regarding the requirements to submit for a CE Mark in Europe. Per that assessment, the product will be designated Class III in the EU and therefore will require submission of a Design Dossier to a Notified Body (NB) for obtaining the CE Mark for the product. This submission will require a detailed device description, a summary of clinical utility for the device, verification data of the device performance, as well as clinical studies to define device performance and safety for the intended use population.

This project must be managed and fully documented under the Design Control process, of ISO 13485 (Section 7.3), which is EU-mandated for most medical devices, and which is similar to the 21 CFR 820 Quality System Regulation of the U.S. FDA. Device performance studies, including laboratory testing and any animal studies that are used to obtain data for formal submission must be done in compliance to applicable ISO or other internationally-recognized standards. The device must be manufactured in compliance to ISO 13485 and sterilized by a validated method under compliance to the applicable international standard. The finished product must be clinically validated for use by the intended users.

ADVA-Tec License

Daré's wholly owned subsidiary, Private Daré, has signed an agreement for a license from ADVA-Tec, Inc. ("ADVA-Tec") for the exclusive right to develop and commercialize Ovaprene® for human contraceptive use worldwide (the "ADVA-Tec Agreement"). The license became effective on July 19, 2017. ADVA-Tec and its affiliates own issued patents or patent applications covering

Ovaprene®, and control proprietary trade secrets covering the manufacture of Ovaprene®. This patent portfolio currently 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 Private Daré. Private Daré also has a right of first negotiation 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 Private Daré to seek a PMA from the FDA, and will supply Private Daré with its requirements of Ovaprene® for clinical and commercial use on commercially reasonable terms.

Under the ADVA-Tec Agreement, Private Daré is required to make payments of up to $14.6 million in the aggregate to ADVA-Tec based on achievement of specified development and regulatory milestones, including completion of a successful PCT 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®; CE 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®, Private Daré 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, Private Daré 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.

Private Daré 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 million in the aggregate over the first three years, and $2.5 million per year thereafter, until a final PMA is filed, or until the first commercial sale of Ovaprene®, whichever occurs first.

The ADVA-Tec license continues on a country-by-country basis until the later of the life of the licensed patents or Private Daré's last commercial sale of Ovaprene®, and the ADVA-Tec Agreement includes customary termination rights for both parties, and provides Private Daré 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 Private Daré fails to do any of the following: (i) satisfy the annual spending obligation described above, (ii) fail to use commercially reasonable efforts to complete all necessary pre-clinical and clinical studies required to support and submit a PMA, (iii) fail to conduct clinical trials as set forth in the development plan that is agreed by Private Daré and ADVA-Tec, and as may be modified by a joint research committee, where such failure is not caused by events outside of Daré' Operations' reasonable control, or (iv) fail to 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 Private Daré' reasonable control. In addition, ADVA-Tec may terminate the ADVA-Tec Agreement if Private Daré develops or commercializes any non-hormonal ring-based vaginal contraceptive device which is deemed competitive to Ovaprene® or, in certain limited circumstances, if Private Daré fails to commercialize Ovaprene® in certain designated countries within three years of the first commercial sale of Ovaprene®. Other than its rights under the ADVA-Tec Agreement, Private Daré does not have any patents or any other material intellectual property assets or licenses.

Manufacturing

ADVA-Tec will be responsible for all activities related to process development and scale up of Ovaprene® manufacturing. Further, either directly or via a contract manufacturing organization ("CMO"), ADVA-Tec will be responsible for Ovaprene® clinical and commercial supply.

Intellectual Property

We actively seek to protect the proprietary technology that we consider important to our business in the United States and other jurisdictions internationally. We also rely upon trade secrets and contracts to protect our proprietary information.

Patents

In accordance with the terms of the ADVA-Tec Agreement, Private Daré is the exclusive licensee of 9 granted U.S. patents and granted patents and/or pending applications in other major markets. There can be no assurance that any of these patent applications will result in the grant of a patent either in the United States or elsewhere, or that any patents granted will be valid and enforceable, or that these patents will provide a competitive advantage or afford protection against competitors with similar technologies. We also rely upon trade secret rights to protect other technologies that may be used to discover, validate and commercialize Ovaprene® and any future product candidates. Daré presently seeks protection, in part, through confidentiality and proprietary information agreements.

Daré considers the following U.S. patents and applications that may be exclusively licensed to Private Daré pursuant to the ADVA-Tec Agreement to be particularly important to the protection of its sole current product candidate, Ovaprene®.

Jurisdiction	Patent Title	Patent Expiration
United States	Intravaginal Ringed Mesh Device And Applicator Therefor	August 2028
United States	Partially Absorbable Fiber-Reinforced Compositions For Controlled Drug Delivery	August 2028
United States	Multicomponent Bioactive Intravaginal Ring	August 2028

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any claim relating to infringement of third party patents that is successfully asserted against Daré, Private Daré, ADVA-Tec or ADVA-Tec's licensor may require Daré to pay substantial damages or may limit Daré's or ADVA-Tec's ability to rely on such patent protection. Any third party claim successfully alleging the invalidity or unenforceability of the patents may also limit Daré's or ADVA-Tec's ability to rely on such patent protection. Even if Daré, Private Daré, ADVA-Tec or ADVA-Tec's licensor were to prevail in any such action, any litigation could be costly and time-consuming and would divert the attention of management and key personnel from Daré's business operations. Also, if our product candidate or any future products are found to infringe the patents of others, our development, manufacture, and sale of these potential products could be severely restricted or prohibited. Because of the importance of the patents licensed to Private Daré by ADVA-Tec for Ovaprene®, our business and our prospects may be harmed if we fail to maintain the patent rights from ADVA-Tec or if we, ADVA-Tec or ADVA-Tec's licensor fail to protect key intellectual property rights.

Trademarks

Private Daré holds a domestic registration for the trademark Daré Bioscience. In accordance with the terms of the ADVA-Tec Agreement, Private Daré is the exclusive licensee of the Ovaprene® trademark.

Market Access

Daré intends to create a comprehensive global commercialization strategy in combination with established pharmaceutical partners and regional distributors. We may or may not elect to participate in commercialization in the United States via a co-promotion arrangement.

Potential future product candidates

In addition to Ovaprene®, Daré has identified other potential product candidates in women's reproductive health that meet the selection criteria of expanding options, improving outcomes, and that are easy and convenient to use. Daré does not currently have any rights or licenses to such product candidates but may seek to license such products in the future to build a product pipeline over time.

Employees

As of August 1, 2017, Daré had three full-time employees, no employees working on a part-time basis, and we anticipate modest growth in staffing prior to 2019. None of Daré's current employees are represented by a labor union or covered by a collective bargaining agreement.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

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

DARÉ BIOSCIENCE, INC.

Date: August 14, 2017 By: /s/ Sabrina Martucci Johnson

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

Date: August 14, 2017 By: /s/ Lisa Walters-Hoffert

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

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of Filing		
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended by Certificate of Amendment dated July 19, 2017 to effect the Reverse Stock Split effective July 20, 2017, and by Certificate of Amendment dated July 19, 2017 stating the name change effective July 20, 2017.					X
3.2	Second Amended and Restated By-laws, effective July 20, 2017	8-K	001-36395	07/20/2017	3.3	
10.1	Lease Termination Agreement dated May 31, 2017, between Cerulean Pharma Inc. and AstraZeneca Pharmaceuticals LP	8-K	001-36395	05/31/2017	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

* Submitted electronically herewith

Exhibit 3.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:43 AM 07/19/2017
FILED 10:43 AM 07/19/2017
SR 20175304876 – File Number 4067151

CERTIFICATE OF AMENDMENT OF THE RESTATED
CERTIFICATE OF INCORPORATION OF CERULEAN PHARMA INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Cerulean Pharma Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Cerulean Pharma Inc. (the "Corporation"), and that the Corporation was originally incorporated pursuant to the General Corporation Law on November 28, 2005 under the name Tempo Pharmaceuticals, Inc. The original Certificate of Incorporation of the Corporation was amended on each of December 1, 2005, October 20, 2006, December 22, 2006, May 8, 2007, December 6, 2007, October 14, 2008, July 9, 2009, July 13, 2009 May 26, 2010, November 12, 2010, December 2, 2011, November 29, 2012, January 11, 2013, February 19, 2013, August 14, 2013, January 30, 2014, February 10, 2014, March 21, 2014, March 28, 2014, March 31, 2014 and March 31, 2014, and amended and restated on April 15, 2014.

2. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law approving this Amendment of the Corporation's Restated Certificate of Incorporation, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that Article FIRST of the Restated Certificate of Incorporation of the Corporation, as amended, be and hereby is deleted in its entirety and the following is inserted in lieu thereof:

"FIRST: Effective as of 12:01 a.m. on July 20, 2017, the name of the Corporation is Dare Bioscience, Inc."

3. This Certificate of Amendment of the Restated Certificate of Incorporation has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 19th day of July, 2017.

/s/ Christopher D. T. Guiffre
Christopher D. T. Guiffre
President and Chief Executive Officer

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:17 AM 07/19/2017
FILED 10:17 AM 07/19/2017
SR 20175304877 – File Number 4067151

CERTIFICATE OF AMENDMENT OF THE RESTATED CERTIFICATE OF INCORPORATION OF CERULEAN PHARMA INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Cerulean pharma Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Cerulean Pharma Inc. (the "Corporation"), and that the Corporation was originally incorporated pursuant to the General Corporation Law on November 28, 2005 under the name Tempo Pharmaceuticals, Inc. The original Certificate of Incorporation of the Corporation was amended on each of December 1, 2005, October 20, 2006, December 22, 2006, May 8, 2007, December 6, 2007, October 14, 2008, July 9, 2009, July 13, 2009, May 26, 2010, November 12, 2010, December 2, 2011, November 29,2012, January 11, 2013, February 19, 2013, August 14, 2013, January 30, 2014, February 10, 2014, March 21, 2014, March 28, 2014, March 31, 2014 and March 31, 2014, and amended and restated on April 15, 2014.

2. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law proposing this Amendment of the Corporation's Restated Certificate of Incorporation and declaring the advisability of this Amendment of the Restated Certificate of Incorporation and authorizing the appropriate officers of the Corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that the first paragraph of Article FOURTH of the Restated Certificate of Incorporation of the Corporation, as amended, be and hereby is deleted in its entirety and the following paragraphs are inserted in lieu thereof:

"FOURTH. Effective as of 12:01 a.m. on July 20, 2017 (the "Effective Time"), a one-for-ten reverse stock split of the Corporation's common stock, par value $0.0001 per share (the "Common Stock"), shall become effective, pursuant to which each ten shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Effective Time and shall represent one share of Common Stock from and after the Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). The par value of the Common Stock following the Reverse Stock Split Shall remain at $0.0001 per share. No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were

issued and outstanding immediately prior to the Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 125,000,000 shares, consisting of (i) 120,000,000 shares of Common Stock, $.0001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $.01 par value per share ("Preferred Stock")."

3. This Certificate of Amendment of the Restated Certificate of Incorporation has been duly adopted by the stockholders of the Corporation in accordance with the provisions of Section 242 of the General Corporation Law.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 19th day of July, 2017.

/s/ Christopher D. T. Guiffre
Christopher D. T. Guiffre
President and Chief Executive Officer

State of Delaware
Secretary of State
Division of Corporation
Delivered 11:19 AM 04/15/2014
FILED 11:13 AM 04/15/2014
SRV 140471255 - 4067151 FILE

RESTATED CERTIFICATE OF INCORPORATION

OF

CERULEAN PHARMA INC.

(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Cerulean Pharma Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Cerulean Pharma Inc. (the "Corporation"), and that the Corporation was originally incorporated pursuant to the General Corporation Law on November 28, 2005 under the name Tempo Pharmaceuticals, Inc. The original Certificate of Incorporation of the Corporation was amended on each of December 1, 2005, October 20, 2006, December 22, 2006, May 8, 2007, December 6, 2007, October 14, 2008, July 9, 2009, July 13, 2009, May 26, 2010, November 12, 2010, December 2, 2011, November 29, 2012, January 11, 2013, February 19, 2013, August 14, 2013, January 30, 2014, February 10, 2014, March 21, 2014, March 28, 2014, March 31, 2014 and March 31, 2014.

2. A resolution was duly adopted by the Board of Directors of the Corporation (the "Board of Directors") pursuant to Sections 242 and 245 of the General Corporation Law proposing this Restated Certificate of Incorporation and declaring the advisability of this Restated Certificate of Incorporation. The stockholders of the Corporation duly approved and adopted this Restated Certificate of Incorporation by written consent in accordance with Sections 228, 242 and 245 of the General Corporation Law.

Accordingly, the Certificate of Incorporation of the Corporation, as previously amended and restated, is hereby further amended and restated in its entirety to read as follows:

FIRST: The name of the Corporation is Cerulean Pharma Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is Corporation Service Company, 2711 Centerville Road, Suite 400, in the City of Wilmington, County of New Castle 19808. The name of its registered agent at that address is Corporation Service Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is 125,000,000 shares, consisting of (i) 120,000,000 shares of Common Stock, $.0001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $.01 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A COMMON STOCK.

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: Except as otherwise provided herein, the Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

SIXTH: In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the By-laws of the Corporation by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present. The stockholders may not adopt, amend, alter or repeal the By-laws of the Corporation, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Certificate of Incorporation, by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By-laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article SIXTH.

SEVENTH: Except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

EIGHTH: The Corporation shall provide indemnification as follows:

1. Actions, Suits and Proceedings Other than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an “Indemnitee”), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

2. Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees) and,

to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

3. Indemnification for Expenses of Successful Party. Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Corporation, (iii) a plea of guilty or nolo contendere by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.

4. Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article EIGHTH. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

5. Advance of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH; and provided further that no such advancement of expenses shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6 of this Article EIGHTH)

that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 of this Article EIGHTH only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2 of this Article EIGHTH, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

7. Remedies. The right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article EIGHTH. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.

8. Limitations. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Corporation shall not indemnify an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. Notwithstanding anything to the contrary in this Article EIGHTH, the Corporation shall not indemnify an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification payments to the Corporation to the extent of such insurance reimbursement.

9. Subsequent Amendment. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

10. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while

holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article EIGHTH. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.

11. Partial Indemnification. If an Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.

12. Insurance. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.

13. Savings Clause. If this Article EIGHTH or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law.

14. Definitions. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

NINTH: This Article NINTH is inserted for the management of the business and for the conduct of the affairs of the Corporation.

1. General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

2. Number of Directors; Election of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the By-laws of the Corporation.

3. Classes of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III at the time such classification becomes effective.

4. Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual

meeting of stockholders at which such director was elected; provided that each director initially assigned to Class I shall serve for a term expiring at the Corporation's first annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; each director initially assigned to Class II shall serve for a term expiring at the Corporation's second annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; and each director initially assigned to Class III shall serve for a term expiring at the Corporation's third annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

5. Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

6. Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law or by this Certificate of Incorporation.

7. Removal. Subject to the rights of holders of any series of Preferred Stock, directors of the Corporation may be removed only for cause and only by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.

8. Vacancies. Subject to the rights of holders of any series of Preferred Stock, any vacancy or newly created directorship in the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such director's earlier death, resignation or removal.

9. Stockholder Nominations and Introduction of Business, Etc. Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the By-laws of the Corporation.

10. Amendments to Article. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By-laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

TENTH: Stockholders of the Corporation may not take any action by written consent in lieu of a meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By-laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article TENTH.

ELEVENTH: Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chairman of the Board or the Chief Executive Officer, and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By-laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article ELEVENTH.

IN WITNESS WHEREOF, this Restated Certificate of Incorporation, which restates, integrates and amends the certificate of incorporation of the Corporation, and which has been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, has been executed by its duly authorized officer this 15th day of April, 2014.

CERULEAN PHARMA INC.

By: /s/ Oliver Fetzer
Name: Oliver Fetzer
Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: August 14, 2017

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lisa Walters-Hoffert, certify that:

1. I have reviewed this Quarterly Report on 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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 14, 2017

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

Exhibit 32.1

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

In connection with the Quarterly Report of Daré Bioscience, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(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 result of operations of the Company.

Date: August 14, 2017

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Daré Bioscience, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Quarterly Report of Daré Bioscience, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(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 result of operations of the Company.

Date: August 14, 2017

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Daré Bioscience, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.