

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

(Mark One)

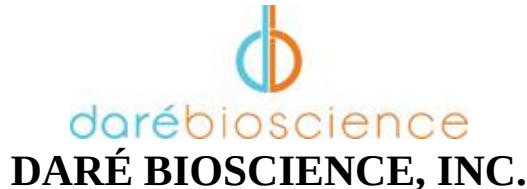
**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **September 30, 2017**

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_



(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36395**  
(Commission  
File Number)

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

**11119 North Torrey Pines Road, Suite 200**  
**La Jolla, CA 92037**

(Address of Principal Executive Offices) (Zip Code)

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

(Former Name or Former Address, 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" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act.

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

As of November 6, 2017 a total of 6,047,161 shares of the Registrant's Common Stock, par value \$0.0001, were issued and outstanding.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, in particular “Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations,” and the information incorporated by reference herein contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would” or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those described in “Risk Factors” and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

- Inability to raise additional capital if needed;
  - Failure to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates due to limited financial resources;
  - Inability to develop and commercialize our product candidates;
  - Failure or delay in completing clinical trials or obtaining United States Food and Drug Administration (“FDA”) or foreign regulatory approval for our product candidates in a timely manner;
  - A change in the FDA’s primary oversight responsibility;
  - Unsuccessful clinical trials stemming from clinical trial designs, failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns;
  - Negative publicity concerning the safety and efficacy of our products in development;
  - Inability to demonstrate sufficient efficacy of product candidates;
  - Reliance on the success of our product candidates;
  - Delays in commencement or completion of clinical trials or suspension or termination of clinical trials;
  - Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;
  - Monetary obligations and other requirements in connection with our exclusive, in-license agreement covering the critical patents and related intellectual property related to our product candidate;
  - Competitors may develop products rendering our product candidates obsolete and noncompetitive;
  - Inability to successfully attract partners and enter into collaborations on acceptable terms;
  - Dependence on third parties to conduct clinical trials and to manufacture product candidates;
  - Dependence on third parties to market and distribute products;
  - Our product candidates, if approved, may not gain market acceptance or obtain adequate coverage for third party reimbursement;
  - A reduction in demand for contraceptives caused by an elimination of current requirements that health insurance plans cover and reimburse FDA-cleared or approved contraceptive products without cost sharing;
  - Difficulty introducing branded product in a market made up of generic products;
-

- Inability to adequately protect or enforce our, or our licensor’s intellectual property rights;
- Disputes or other developments concerning our intellectual property rights;
- Actual and anticipated fluctuations in our quarterly or annual operating results;
- Price and volume fluctuations in the overall stock markets;
- Litigation or public concern about the safety of our potential products;
- Strict government regulations on our business;
- Regulations governing the production or marketing of our product candidates;
- Loss of, or inability to attract, key personnel; and
- Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. You should also read carefully the factors described in the section “Risk Factors” of this Quarterly Report on Form 10-Q and “Item 1A. Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our subsequent Current Reports on Form 8-K, press releases, and our website. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

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**PART I— FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements.**

**Daré Bioscience, Inc. and Subsidiaries**  
**Condensed Consolidated Balance Sheets**

	September 30, 2017 (unaudited)	December 31, 2016
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 8,529,220	\$ 44,614
Other receivables	710,692	—
Prepaid expenses and other current assets	1,143,373	—
Total current assets	10,383,285	44,614
Goodwill	12,880,574	—
Other non-current assets	2,800	—
Total assets	<u>\$ 23,266,659</u>	<u>\$ 44,614</u>
<b>Liabilities and Stockholders' equity (deficit)</b>		
<b>Current Liabilities</b>		
Accounts payable and accrued expenses	\$ 839,374	\$ 12,678
Convertible promissory notes	—	697,500
Interest payable	—	45,057
Total current liabilities	839,374	755,235
Deferred rent	157	—
Total liabilities	<u>839,531</u>	<u>755,235</u>
<b>Commitments and contingencies (Note 6)</b>		
<b>Stockholders' equity (deficit)</b>		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized		
None issued and outstanding	—	—
Common stock: \$0.0001 par value, 120,000,000 shares authorized, 6,047,161 shares issued and outstanding at September 30, 2017 and \$0.001 par value, 10,000,000 shares authorized, 910,000 shares issued and outstanding at December 31, 2016	605	91
Accumulated other comprehensive loss	(9,774)	—
Additional paid-in capital	25,535,872	17,123
Accumulated deficit	(3,099,575)	(727,835)
Total stockholders' equity (deficit)	<u>22,427,128</u>	<u>(710,621)</u>
<b>Total liabilities and stockholders' equity (deficit)</b>	<u>\$ 23,266,659</u>	<u>\$ 44,614</u>

See Accompanying Notes to Interim Condensed Consolidated Financial Statements.

The operations presented in the Interim Condensed Consolidated Financial Statements and Accompanying Notes for the three months ended September 30, 2017 represent the operations of the Company following the Stock Purchase Transaction. The Interim Condensed Consolidated Financial Statements and Accompanying Notes for the three months ended September 30, 2016 represent the operations of the Company when it was private, making a comparison between periods difficult.

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Operating expenses:				
General and administrative	\$ 1,052,628	\$ 5,963	\$ 1,729,338	\$ 119,283
Research and development expenses	280,793	—	312,169	72,666
License expenses	—	—	—	250,000
Total operating expenses	<u>1,333,421</u>	<u>5,963</u>	<u>2,041,507</u>	<u>441,949</u>
Loss from operations	(1,333,421)	(5,963)	(2,041,507)	(441,949)
Interest income (expense)	(296,262)	(10,142)	(330,233)	(30,205)
Net loss	<u>\$ (1,629,683)</u>	<u>\$ (16,105)</u>	<u>\$ (2,371,740)</u>	<u>\$ (472,154)</u>
Other comprehensive loss, net of tax:				
Foreign currency translation adjustments	\$ (9,774)	\$ —	\$ (9,774)	\$ —
Comprehensive loss	<u>\$ (1,639,457)</u>	<u>\$ (16,105)</u>	<u>\$ (2,381,514)</u>	<u>\$ (472,154)</u>
Loss per common share - basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.02)</u>	<u>\$ (1.04)</u>	<u>\$ (0.58)</u>
Weighted average number of common shares outstanding:				
Basic	<u>4,986,226</u>	<u>820,000</u>	<u>2,283,673</u>	<u>820,000</u>
Diluted	<u>5,638,153</u>	<u>830,519</u>	<u>2,935,600</u>	<u>830,519</u>

*See Accompanying Notes to Interim Condensed Consolidated Financial Statements.*

The operations presented in the Interim Condensed Consolidated Financial Statements for the three months ended September 30, 2017 represent the operations of the Company following the Stock Purchase Transaction. The Interim Condensed Consolidated Financial Statements for the three months ended September 30, 2016 represent the operations of the Company when it was private, making a comparison between periods difficult.

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

	Nine months ended September 30,	
	2017	2016
<b>Operating activities:</b>		
Net loss for period	\$ (2,371,740)	\$ (472,154)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	6,953	3
Non-cash interest	316,804	—
Changes in operating assets and liabilities, net impact of acquisition:		
Other receivables	—	250,000
Prepaid expenses and other current assets	(224,433)	—
Other assets	(2,800)	—
Accounts payable and accrued expenses	659,223	(13,401)
Interest payable	36,776	30,205
Deferred rent	157	—
Net cash used in operating activities	<u>(1,579,060)</u>	<u>(205,347)</u>
<b>Investing activities:</b>		
Cash acquired through merger	9,918,440	—
Net cash provided by investing activities	<u>9,918,440</u>	<u>—</u>
<b>Financing activities:</b>		
Proceeds from issuance of convertible promissory notes	155,000	—
Net cash provided by financing activities	<u>155,000</u>	<u>—</u>
Effect of exchange rate changes on cash and cash equivalents	(9,774)	—
Net increase (decrease) in cash and cash equivalents	8,484,606	(205,347)
Cash and cash equivalents, beginning of period	44,614	219,413
Cash and cash equivalents, end of period	<u>\$ 8,529,220</u>	<u>\$ 14,066</u>

*See Accompanying Notes to Interim Condensed Consolidated Financial Statements.*

The operations presented in the Interim Condensed Consolidated Financial Statements for the three months ended September 30, 2017 represent the operations of the Company following the Stock Purchase Transaction. The Interim Condensed Consolidated Financial Statements for the three months ended September 30, 2016 represent the operations of the Company when it was private, making a comparison between periods difficult.

## **1. Description of Business and Basis of Presentation**

### ***Description of Business***

Daré Bioscience, Inc. (“Daré” or the “Company”), 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.

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 issued and outstanding shares of the Company’s shares of common stock.

On July 20, 2017, the Company effected a 1-for-10 reverse stock split of its 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 operations presented in the accompanying condensed consolidated financial statements and related notes for the period ending September 30, 2017 represent the operations of the Company and give effect to the Stock Purchase Transaction, including stock-based compensation awards. The condensed consolidated financial statements and related notes for all periods prior to the Stock Purchase Transaction represent the operations of Private Daré, making a comparison between historical and recent periods difficult.

Following the Stock Purchase Transaction, the Company began trading on the Nasdaq Capital Market under the symbol “DARE.” Prior to the Stock Purchase Transaction, the Company traded under the symbol “CERU.”

### ***Basis of presentation***

The condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) as defined by the Financial Accounting Standards Board (“FASB”). These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2016 that were attached as Exhibit 99.1 to the Company’s Amendment No. 1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission (“SEC”) on October 2, 2017.



## ***Unaudited Interim Financial Information***

The interim condensed consolidated financial statements included in this document are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of September 30, 2017, and its results of operations for the three and nine months ended September 30, 2017 and 2016, and cash flows for the nine months ended September 30, 2017 and 2016. The results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other future annual or interim period. The December 31, 2016 consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2016.

## **2. Summary of Significant Accounting Policies**

### ***Liquidity***

As of September 30, 2017, the Company had an accumulated deficit of approximately \$3.10 million. The Company also had negative cash flow from operations of approximately \$1.58 million during the nine months ended September 30, 2017. The Company had cash and cash equivalents of approximately \$8.53 million as of September 30, 2017. The Company will need additional capital to further fund the development of, and seek regulatory approvals for, its current product candidate and any future candidates it may license as well as to commercialize any approved products.

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

If additional funding is not available on a timely basis or at adequate levels, the Company will need to reevaluate its operating plans. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### ***Principles of Consolidation***

The condensed consolidated financial statements of the Company are stated in U.S. dollars and are prepared using U.S. GAAP. These financial statements include the accounts of the Company and its wholly owned subsidiaries, Daré Bioscience Operations, Inc., and Daré Bioscience Australia PTY LTD. The financial statements of the Company's wholly owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in Accumulated Other Comprehensive Income. All intercompany transactions and accounts have been eliminated in consolidation.

### ***Use of Estimates***

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

### ***Risks and Uncertainties***

The Company will require approvals from the U.S. Food and Drug Administration or foreign regulatory agencies prior to being able to sell any products. There can be no assurance that the Company's current or future product candidates will receive the necessary approvals. If the Company is denied regulatory approval of its product candidates, or if approval is delayed, it may have a material adverse impact on the Company's business, results of operations and its financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the ability to license product candidates, successfully develop product candidates, raise additional capital, compete with other products, and protect proprietary technology. In the event the Company receives a regulatory approval for a product, the market's acceptance of the product remains a risk. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

For a more comprehensive list of risk factors, please refer to the Company's interim report on Form 10-Q for the quarterly period ended June 30, 2017.

### ***Cash and Cash Equivalents***

The Company considers cash and all highly liquid debt instruments with an original maturity of three months or less to be cash and cash equivalents.

### ***Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents. The Company places its cash and cash equivalents with a limited number of high quality financial institutions and at times may exceed the amount of insurance provided on such deposits. The Company has not experienced any loss on deposits of cash and cash equivalents.

### ***Business Combinations***

Assets acquired, and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of the total purchase consideration over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on all available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

### ***Goodwill***

Goodwill is not amortized but is tested annually for impairment or more frequently if impairment indicators exist. The Company adopted accounting guidance related to annual and interim goodwill impairment tests which allows the Company to first assess qualitative factors before performing a quantitative assessment of the fair value of a reporting unit. If it is determined on the basis of qualitative factors that the fair value of the reporting unit is more likely than not less than the carrying amount, a quantitative impairment test is required. The Company recorded goodwill of approximately \$12.88 million related to the Stock Purchase Transaction, from the acquisition date, July 19, 2017. The Company assessed goodwill at September 30, 2017 and determined there was no impairment during the period.

### **Segment Reporting**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. Our chief operating decision maker is the chief executive officer. The Company has one operating segment, women's reproductive health.

### **Fair Value of Financial Instruments**

Certain assets and liabilities are carried at fair value in accordance with Accounting Standards Codification ("ASC") 820, Fair Value Measurement. 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 must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy is based on three levels of inputs which are used to measure fair value, of which the first two levels are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's instruments that are carried at fair value are cash and cash equivalents, accounts payable and accrued interest. The carrying values of accounts payable and accrued interest approximate their fair value due to the short-term nature of these liabilities.

### **Net Loss Per Share**

Basic net loss attributable to common stockholders per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period without consideration of common stock equivalents. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods presented as the inclusion of all potential dilutive securities would have been antidilutive. All per share figures have been retroactively adjusted for the Reverse Stock Split.

### **Stock-Based Compensation**

The Company records compensation expense for all stock-based awards granted based on the fair value of the award at the time of grant. The Company uses the Black-Scholes Pricing Model to determine the fair value of each of the awards which considers factors such as expected term, volatility, risk free interest rate and dividend yield. Due to the limited history of the Company, the simplified method was utilized in order to determine the expected term of the awards. Additionally, the Company considered comparable companies in the industry which have available share price history to calculate the volatility. The Company compared U.S. Treasury Bills in determining the risk-free interest rate appropriate given the expected term. Finally, the Company has not established and has no plans to establish a dividend policy or declare any dividends in the foreseeable future and thus no dividend yield was determined necessary in the calculation of fair value.

## **Income Taxes**

The Company accounts for income taxes using the asset and liability method in accordance with ASC 740, Income taxes. Under this method deferred income taxes are provided to reflect the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company follows the two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not, that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount, which is more than 50% likely of being realized upon ultimate settlement. The Company considers many factors when evaluating and estimating the Company's tax positions and tax benefits, which may require periodic adjustments. At September 30, 2017, the Company did not record any liabilities for uncertain tax positions.

As the Company has significant operating losses, the Company does not expect to pay any income taxes for 2017 and as such no income tax provision has been made. Management evaluated the Company's tax positions and concluded that the Company had taken no uncertain tax positions that require adjustment to the financial statements. The tax years 2015 to 2016 remain open to examination by federal and state taxing authorities.

## **Recent Accounting Pronouncements**

On May 28, 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue From Contracts With Customers*, which impacts the way in which some entities recognize revenue for certain types of transactions. The new standard will become effective beginning in 2018 for public companies. As the Company does not currently have any contracts with customers we do not expect any impact from this accounting standard.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. The new standard is effective for public companies for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently assessing the potential impact of this accounting standard and the effect it might have on the financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which intended to add or clarify guidance on the classification of certain cash receipts and payments on the statement of cash flows. The new guidance addresses cash flows related to the following: debt prepayment or extinguishment costs, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies and bank-owned life insurance policies, distributions received from equity method investees, beneficial interest in securitization transactions, and the application of predominance principle to separately identifiable cash flows. The standard is effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those fiscal years with early adoption permitted. Daré is currently evaluating the effect of this new guidance on its financial statements.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which intended to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard is effective for Daré for annual periods beginning after December 15, 2017. Daré's early adoption of this standard did not have a material impact on the Company's financial statements.

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

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*, which intended to provide clarity when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for the Daré for annual periods beginning on or after December 15, 2017 with early adoption permitted. The Company's early adoption of this standard did not have a material impact on the Company's financial statements.

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

### **3. Acquisitions**

On July 19, 2017, Private Daré completed the Stock Purchase Transaction with Cerulean as discussed in Note 1. For purposes of clarity, prior to the Stock Purchase Transaction, we sometimes refer to the Company as Cerulean. The Stock Purchase Transaction was accounted for as a reverse merger under the acquisition method of accounting whereby Private Daré was considered to have acquired Cerulean for financial reporting purposes because immediately upon completion of the Stock Purchase Transaction, Private Daré stockholders held a majority of the voting interest of the combined company. Pursuant to business combination accounting, the Company applied the acquisition method, which requires the assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The excess of the purchase price over the assets acquired and liabilities assumed represents goodwill. The goodwill is primarily attributable to the cash and cash equivalents at closing of approximately \$9.92 million and the impact of the unamortized fair value of Cerulean stock options of approximately \$3.65 million. The unamortized fair value of the Cerulean stock options relates to an option modification approved on March 19, 2017 that provided for an acceleration of vesting upon a change in control event. Such modification became effective upon the completion of the Stock Purchase Transaction. Hence, the unamortized fair value of such options is deemed to be part of total purchase consideration and goodwill. Transaction costs associated with the Stock Purchase Transaction of \$963,380 are included in general and administrative expense. The total purchase price consideration of approximately \$24.28 million represents the fair value of the shares of Cerulean stock issued in connection with the Stock Purchase Transaction and the unamortized fair value of Cerulean options assumed on July 19, 2017 which was allocated as follows:

<b>Purchase Consideration</b>	<b>(in thousands)</b>	
Fair value of shares issued	\$	20,625
Unamortized fair value of Cerulean options		3,654
Fair value of total consideration	\$	24,279
<b>Assets acquired and liabilities assumed</b>		
Cash and cash equivalents	\$	9,918
Prepaid expense and other current assets		1,689
Accounts payable		(209)
Total assets acquired and liabilities assumed		11,398
Goodwill	\$	<b>12,881</b>

The final allocation of the purchase price is dependent on the finalization of the valuation of the fair value of assets acquired and liabilities assumed and may differ from the amounts included in these financial statements. The Company expects to complete the final allocation as soon as practical but no later than one year from the acquisition date.

#### **4. Convertible Promissory Notes**

On December 4, 2015, Private Daré issued convertible promissory notes in the aggregate principal amount of \$500,000. The convertible promissory notes accrue interest at a rate of 8% per annum, are convertible into Private Daré's next preferred stock financing round and are payable following the delivery of a demand by the holders of a majority in interest of the outstanding principal (including the outstanding principal amount under the convertible promissory notes issued on or after November 18, 2016, as described further below) on or after December 4, 2017. In the event of a preferred stock financing, all outstanding principal and unpaid interest under the convertible promissory notes will convert into the shares of Private Daré's preferred stock issued in such financing at the price per share paid by the purchasers of such shares and an additional number of shares equal to 15% to 25% of the outstanding principal and unpaid interest based on the amount of time that has passed between the issuance of the convertible promissory notes and the closing of such preferred stock financing.

During the week of November 18, 2016, Private Daré's issued additional convertible promissory notes, and amended the terms of certain of the outstanding convertible promissory notes held by persons who purchased additional convertible promissory notes on or after November 18, 2016. These convertible promissory notes (including the convertible promissory notes issued in December 2015 and amended in connection with the sale of additional convertible promissory notes in November 2016) accrue interest at a rate of 8% per annum, are convertible into Private Daré's next preferred stock financing round and are payable following the delivery of a demand by the holders of a majority in interest of the outstanding principal (including the outstanding principal amount under the convertible promissory notes issued in December 2015) on or after December 4, 2017. In the event of a preferred stock financing, all outstanding principal and unpaid interest under the convertible promissory notes (including the amended convertible promissory notes originally issued in December 2015) will convert into the shares of Private Daré's preferred stock issued in such financing at the price per share paid by the purchasers of such shares and an additional number of shares equal to 40% of the outstanding principal and unpaid interest. In addition, in the event of a change of control in which the convertible promissory notes (including the amended convertible promissory notes originally issued in December 2015) are repaid, the holders of such notes are entitled to receive 2 to 5 times the amount of the principal based on the proceeds payable to Private Daré or its stockholders in connection with such change of control. During the week of November 18, 2016, Private Daré issued convertible promissory notes in the aggregate principal amount of \$197,500 and amended the terms of prior notes in the aggregate principal amount of \$275,000 to correspond with the terms of such additional convertible promissory notes. On February 17, 2017 the Company issued an additional convertible promissory note in the principal amount of \$100,000.

In connection with the Stock Purchase Transaction, described in further detail below, all outstanding convertible promissory notes issued prior to March 31, 2017 were further amended to provide that such notes will convert into shares of Private Daré common stock at a price per share of \$0.18727 (subject to stock splits, combinations and similar events) effective as of immediately prior to the closing of the Stock Purchase Transaction and that the Stock Purchase Transaction would not constitute a change of control, including for purposes of the repayment premium described above.

On July 19, 2017, Private Daré amended the notes to provide that (i) the interest on the notes be subject to compounding on an annual basis as of December 31 of each year and (ii) the number of shares of common stock issuable upon conversion of the convertible promissory notes issued prior to March 31, 2017 will be equal to the outstanding principal amount plus accrued interest through March 31, 2017 divided by \$0.18727 (subject to stock splits, combinations and similar events) plus, in the case of the convertible promissory notes issued in December 2015, 25% of the principal amount plus accrued interest through March 31, 2017 divided by \$0.18727 (subject to stock splits, combinations and similar events), and, in the case of the convertible promissory notes issued on or after November 18, 2016 (including certain of the amended convertible promissory notes originally issued in December 2015 the holders of which also participated in the November 2016 note offering), 40% of the principal amount plus accrued interest through March 31, 2017 divided by \$0.18727 (subject to stock splits, combinations and similar events).

Between April 1, 2017 and June 6, 2017 Private Daré issued additional convertible promissory notes in the aggregate principal amount of \$55,000 pursuant to a new note purchase agreement. One note in the principal amount of \$20,000 was issued on May 31, 2017 and two notes in the aggregate principal amount of \$35,000 were issued during the first week of June. The new note purchase agreement provides for one or more additional closings through the earlier to occur of September 28, 2017 and the date on which the Company's stockholders approve the Stock Purchase Transaction, and limits the aggregate principal amount of the convertible promissory notes issued thereunder to \$2.0 million. The convertible promissory notes issued pursuant to the May 31, 2017 note purchase agreement bear an annual interest rate of 8% and will automatically convert immediately prior to closing of the transaction into the number of shares of Private Daré common stock equal to 120% of the original principal amount of each such note divided by \$0.38. The interest on such notes will not convert into shares of Private Daré's common stock. In addition, the holders of such notes issued pursuant to the new note purchase agreement are entitled to convert the value of any then outstanding notes plus unpaid and accrued interest plus an additional 20% of the principal amount of their notes into Qualified and Non-Qualified Equity Financings (with such terms having the same meaning as in the December 2015 note purchase agreement) at the price paid by investors in the Qualified and Non-Qualified Equity Financings. Each purchaser of notes pursuant to the new note purchase agreement also executed and delivered a counterpart signature page to the Stock Purchase Agreement.

Immediately prior to the closing of the Stock Purchase Transaction, all of the convertible promissory notes of Private Daré, in aggregate principal of, and accrued interest on, were converted into shares of common stock of Private Daré and all of the outstanding shares of common stock of Private Daré were exchanged for shares of common stock of the Company pursuant to the exchange ratio defined in the Stock Purchase Agreement. As a result of the conversion, the Company recognized an expense of \$316,804 relating to the beneficial conversion feature present in each of the note agreements.

## **5. Stock-based Compensation**

Prior to the Stock Purchase Transaction, the 2015 Employee, Director and Consultant Equity Incentive Plan of Private Daré, (the "2015 Plan") governed the issuance of incentive stock options, non-qualified stock options, stock grants and stock-based awards to individuals who were then employees, officers, non-employee directors or consultants of the Company. Upon closing of the Stock Purchase Transaction, the 2015 Plan was assumed by the Company and each outstanding option to acquire stock of Private Daré that was not exercised prior to the closing of the Stock Purchase Transaction was assumed on the same terms and conditions as were applicable under the 2015 Plan, and became an option to acquire such shares of the Company's common stock as was equal to the number of Private Daré shares subject to such unexercised option multiplied by the exchange ratio defined in the Stock Purchase Agreement, at a correspondingly adjusted exercise price.

#### *Stock Options Under the 2015 Plan of Private Daré (the 2015 Plan)*

Options granted under the 2015 Plan have terms of ten years from the date of grant unless earlier terminated and generally vest over a three-year period. There were no options granted under the 2015 Plan during the nine months ended September 30, 2017 and effective as of July 19, 2017 following closing of the Stock Purchase Transaction, no further options may be granted under the 2015 Plan.

The exercise price of the 50,000 options granted for the year ended December 31, 2016 was equal to the estimated fair value of the common stock of Private Daré on the date of grant. On July 19, 2017, these options in Private Daré were assumed by the Company and 10,148 options were outstanding as of September 30, 2017 after adjustments for the Stock Purchase Transaction and Reverse Stock Split.

#### *Stock Options Under the 2014 Plan (the Current Plan)*

Options granted under the Company's 2014 Stock Incentive Plan (the "2014 Plan" or "Current Plan") have terms of no more than ten years from the date of grant unless earlier terminated.

The Company's board of directors approved two modifications to the stock options issued under the 2014 Plan to participants who were providing services to the Company as of March 19, 2017. The Company extended the exercise period for such stock options to two years beyond such participant's termination date, unless the original option terms provided for a longer exercise period, and provided for the acceleration of vesting for such stock options upon a change in control event (such as the Stock Purchase Transaction). Modifications to the existing option terms resulted in unamortized fair value expense of approximately \$3.7 million and was recorded as part of the total consideration in the Stock Purchase Transaction and discussed in Note 3.

As part of the Stock Purchase Transaction, 544,040 Cerulean stock options were assumed by the Company and remain outstanding as of September 30, 2017. Together with the Private Daré options assumed in connection with the Stock Purchase Transaction, the Company had 554,040 options outstanding as of September 30, 2017.

A summary of stock option activity with regards to the 2015 Plan and the Current Plan, and related information for the nine months ended September 30, 2017 is as follows:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2016	412,248	\$ 42.04
Granted	156,349	8.11
Exercised	—	—
Cancelled/expired	(14,557)	51.38
Outstanding at September 30, 2017 (unaudited)	<u>554,040</u>	<u>29.93</u>
Exercisable at September 30, 2017 (unaudited)	<u>545,640</u>	<u>\$ 32.62</u>

Options outstanding and exercisable at September 30, 2017 had a weighted average contractual life of 8.15 years. As of September 30, 2017, \$44,460 represents unamortized stock-based compensation expense which will be amortized over the weighted average period of 1.79 years.

#### *Compensation Expense*

The Company has recorded stock-based compensation expense related to the issuance of stock option awards to employees of \$6,947 for the three months ended September 30, 2017 with no comparable expense in the same period of the prior year, and \$6,953 and \$3 for the nine months ended September 30, 2017 and 2016, respectively. There were no stock options granted during the three or nine months ended September 30, 2016.

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the three and nine months ended September 30, 2017 are as follows:



	Three months ended September 30, 2017	Nine months ended September 30, 2017
Expected life in years	10.0	4.6-10
Risk-free interest rate	2.26%	1.7-2.4%
Expected volatility	127%	67%-127%
Forfeiture rate	23.6%	1.86%-29.9%
Dividend yield	0.0%	0.0%
Weighted-average fair value of options granted	\$ 6.30	\$ 4.49

#### *Restricted Stock After the Stock Purchase Transaction*

The 3.14 million shares of common stock issued in connection with the Stock Purchase Transaction to the shareholders of Private Daré have not been registered with the SEC and may only be sold pursuant to an exemption from the SEC's registration requirements. Some of these shares may become eligible for sale beginning six months after the date of the Stock Purchase Transaction pursuant to Rule 144.

#### *Common Stock Warrants*

No warrants were exercised during the nine months ended September 30, 2017. The following table summarizes the outstanding warrants for the Company's common stock as of September 30, 2017:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
169	\$ 17.70	August 8, 2018
2,906	\$ 12.04	December 1, 2021
3,737	\$ 12.04	December 6, 2021
17,190	\$ 6.05	January 8, 2020
6,500	\$ 1.00	April 4, 2026
30,502		

## **6. Commitments and Contingencies**

### **Operating Leases**

The Company entered into a lease agreement that commenced on January 1, 2017 and provided for termination by either party upon 30 days' notice. In July 2017, the Company provided notice of termination of this lease agreement.

The Company entered into a new sublease agreement on July 27, 2017 which provides facilities space as well as other administrative services for a monthly fee of \$5,651 that increases 3% annually. The sublease agreement commenced on August 1, 2017 and expires on June 30, 2019. The parties have agreed to negotiate in good faith for an extension of this sublease agreement under similar terms. The Company may terminate the sublease by providing 30 days' written notice.

### **Other Legal Contingencies**

From time to time, the Company may be involved in various claims arising in the normal course of business. Management is not aware of any material claims, disputes or unsettled matters that would have a material adverse effect on the Company's results of operations, liquidity or financial position that the Company has not adequately provided for in the accompanying financial statements.

## **Risk Management**

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure to these risks to an acceptable level.

## **Employment Agreements**

Certain executive officers are entitled to payments if they are terminated without cause or as a result of a change in control of the Company. Upon termination without cause, and not as a result of death or disability, each officer is entitled to receive a payment of an amount equal to six to twelve months of base salary and to receive continuing health benefits coverage for periods ranging between six to twelve months following the termination of employment or until such officer is covered under a separate plan from another employer. Upon termination other than for cause or for good reason within three months prior or twelve months following a change in control of the Company, each officer will be entitled to receive a payment of an amount equal to nine to eighteen months of base salary and target bonus and to receive continuing health benefits coverage for periods ranging between nine to eighteen months following the termination of employment. In addition, upon a change in control of the Company, each officer's outstanding unvested options shall fully vest and accelerate subject to the conditions outlined in such officer's employment agreement.

## **License and Royalty Agreements**

The Company signed an agreement to obtain a license from ADVA-Tec (the "*ADVA-Tec Agreement*") for the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide that became effective once the initial funding called for by the ADVA-Tec Agreement was secured. ADVA-Tec and its affiliates own issued patents or patent applications covering Ovaprene, and control proprietary trade secrets covering the manufacture of Ovaprene. As of the date of these financial statements, this patent portfolio includes 12 issued patents worldwide, along with 8 patent applications, all of which are exclusively licensed to the Company in accordance with the terms of the ADVA-Tec Agreement. The Company also has a right of first refusal to license these patents and patent applications for purposes of additional indications for Ovaprene. Under the ADVA-Tec Agreement, ADVA-Tec will conduct certain research and development work as necessary to allow the Company to seek a Premarket Approval ("PMA") from the United States Food and Drug Administration ("FDA"), and will supply the Company with its requirements of Ovaprene for clinical and commercial use on commercially reasonable terms.

Under the ADVA-Tec Agreement, the Company is required to make payments of up to \$14.6 million in the aggregate to ADVA-Tec based on the achievement of specified development and regulatory milestones, which include the completion of a successful Postcoital Clinical Trial ("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; Conformite Europeene ("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, the Company is also required to make royalty payments to ADVA-Tec based on aggregate annual net sales of Ovaprene in specified regions, which percentage royalty rate will vary between 1% and 10% and will increase based on various net sales thresholds. Finally, the Company is also required to make up to \$20.0 million in the aggregate in commercial milestone payments to ADVA-Tec upon reaching certain worldwide net sales milestones.

The Company is obligated to use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, such amounts totaling \$5.0 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

The ADVA-Tec license continues on a country-by-country basis until the later of the life of the licensed patents or the Company's last commercial sale of Ovaprene, and the ADVA-Tec Agreement includes customary termination rights for both parties, and provides the Company the right to terminate with or without cause in whole or on a country-by-country basis upon 60 days prior written notice. In addition, ADVA-Tec may terminate the ADVA-Tec Agreement if the Company fails to do any of the following: (i) satisfy the annual spending obligation described above, (ii) 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 Daré and ADVA-Tec, and as may be modified by a joint research committee, where such failure is not caused by events outside of the Company's reasonable control, or (iv) 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 the its reasonable control. In addition, ADVA-Tec may terminate the ADVA-Tec Agreement if the Company develops or commercializes any non-hormonal ring-based vaginal contraceptive device which is deemed competitive to Ovaprene or, in certain limited circumstances, if the Company fails to commercialize Ovaprene in certain designated countries within three years of the first commercial sale of Ovaprene.

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

*The following discussion and analysis of financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements of Daré Bioscience, Inc. and accompanying notes appearing elsewhere in this report. For additional context with which to understand our financial condition and results of operations, see the discussion and analysis included in the discussion and analysis included in our Current Report on Amendment No. 1 to Form 8-K filed with the SEC on October 2, 2017, and the unaudited condensed consolidated financial statements and accompanying notes contained therein. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including but not limited to those identified under "Forward Looking Statements" below, those discussed in Item 1A Risk Factors of Part II of this report and included in "Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. Ovaprene™ is a trademark licensed by our company. All trademarks, service marks or trade names appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, service marks or trade names is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark or trade name owners.*

### Overview

Daré Bioscience, Inc. ("Daré," "we," "us," "our," and "our Company"), a Delaware corporation, was formed on November 28, 2005. The Company and its wholly owned subsidiaries, Daré Bioscience Operations, Inc. and Daré Bioscience Australia Pty LTD, operate in one segment with its principal office in San Diego, California. The Company is a healthcare company committed to the development and commercialization of innovative products in women's reproductive health. The Company seeks product candidates that expand options, improve outcomes and are easy for women to use. The Company's first product candidate is Ovaprene, a non-hormonal contraceptive intravaginal ring intended to provide protection over multiple weeks of use, requiring no intervention at the time of intercourse.

Since our inception, we have devoted significant resources to license and prepare for the development of Ovaprene. As of September 30, 2017, Daré had cash of approximately \$8.53 million. We will continue to require additional capital to continue our clinical development activities, expand our product portfolio and if successful, to commercialize approved products. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to advance Ovaprene and to acquire or license the rights to other potential product candidates.

### Recent Events

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 the Company in accordance with the terms of a stock purchase agreement dated as of March 19, 2017 (the "Stock Purchase Agreement"), by and among the Company, Private Daré and the holders of capital stock and securities convertible into capital stock of Private Daré named therein (the "Private Daré Stockholders"). Pursuant to the Stock Purchase Agreement, each Private Daré Stockholder sold its shares of common stock in Private Daré to the Company in exchange for newly issued shares of the Company's common stock.

On July 19, 2017, the Company 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, the Company 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 issued and outstanding shares of the Company's shares of common stock.

Immediately prior to the closing of the Stock Purchase Transaction, all the convertible promissory notes, principal and accrued interest of Private Daré were converted into shares of common stock of Private Daré at conversion prices of \$0.18 and \$0.36 per share in accordance with their respective note agreements.

In addition, the holders of the convertible promissory notes received additional common shares of Private Daré ranging from 20% to 40% of total outstanding principal and accrued interest as of the date of conversion. All outstanding shares of common stock of Private Daré were exchanged for newly-issued shares of common stock of the Company and outstanding stock options of Private Daré were assumed by the Company pursuant to the terms of the Stock Purchase Transaction. For purposes of clarity, we sometimes refer to our business as “Private Daré” when discussing the results of operations and financial condition when we were a private company prior to the Stock Purchase Transaction.

Immediately after the Stock Purchase Transaction, the Company implemented a reverse stock split (“Reverse Stock Split”) at a ratio of one new share for every ten shares of its common stock outstanding. No fractional shares were issued and instead, shareholders received cash for the value of their fractional shares. Following the closing of the Stock Purchase Transaction, the previous Cerulean equity holders of the Company immediately prior to the closing of the Stock Purchase Transaction owned approximately 49% and equity holders of Private Daré owned approximately 51% of the shares of the Company.

## **Financial Operations Overview**

### ***Research and Development Expenses***

Research and development expenses represent costs incurred to conduct research and development of Daré’s product candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- expenses incurred under agreements with consultants and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies; and
- internal costs that are associated with activities performed by our research and development organization and generally benefit multiple programs.

Daré expects research and development expenses will increase in the future as we advance Oviparene or other potential product candidates into and through clinical trials and as we pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing and inventory build-up related costs. In addition, Daré continues to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fee and/or milestone payments.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidates. The probability of success of Daré’s product candidates may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we are unable to accurately determine the duration and completion costs of development projects or when and to what extent we will generate revenue from the commercialization of any of our product candidates.

### ***General and Administrative Expense***

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs. Daré expects to incur additional expenses as a result of increased costs associated with being a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance, investor relations, and other administrative expenses and professional services.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, Daré evaluates these estimates and judgments. We base our estimates on historical experience and on various assumptions that Daré believes to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. Daré believes that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

### **Results of Operations — Comparison of Three Months Ended September 30, 2017 and 2016**

The operations presented in the interim condensed consolidated financial statements and accompanying notes for the three months ended September 30, 2017 represent the operations of the Company following the Stock Purchase Transaction. The interim condensed consolidated financial statements and accompanying notes for the three months ended September 30, 2016 represent the operations of Private Daré, making a comparison between periods difficult.

The following table summarizes Daré's consolidated results for the three months ended September 30, 2017 and 2016, together with the changes in those items in dollars:

	<u>Three months ended September 30,</u>		<u>Change</u>
	<u>2017</u>	<u>2016</u>	<u>Dollars</u>
Operating expenses:			
General and administrative	\$ 1,052,628	\$ 5,963	1,046,665
Research and development expenses	280,793	—	280,793
Total operating expenses	<u>1,333,421</u>	<u>5,963</u>	<u>1,327,458</u>
Loss from operations	<u>(1,333,421)</u>	<u>(5,963)</u>	<u>(1,327,458)</u>
Interest income (expense)	<u>(296,262)</u>	<u>(10,142)</u>	<u>(286,120)</u>
Net Loss	<u>\$ (1,629,683)</u>	<u>\$ (16,105)</u>	<u>(1,613,578)</u>
Other comprehensive loss:			
Foreign currency translation adjustments	\$ (9,774)	\$ —	(9,774)
Comprehensive loss	<u>\$ (1,639,457)</u>	<u>\$ (16,105)</u>	<u>(1,623,352)</u>

#### **General and administrative**

General and administrative expenses increased by \$1,046,665 to \$1,052,628 for the three months ended September 30, 2017 from \$5,963 for the three months ended September 30, 2016. The increase was primarily due to \$535,003 of legal expense, accounting expense and other expenses incurred in connection with the Stock Purchase Transaction. Daré personnel costs increased \$319,197 due to salaries expense in the current period, including bonuses, with no comparable expense in the same period of the prior year. Following the Stock Purchase Transaction, and based upon the market data presented and recommendation of Radford, the Company's compensation consultant, and upon approval of the Compensation Committee of the Company's Board of Directors, the Company began paying its newly appointed executives compensation at a level in line with market rates for executive officers of early stage, pre-commercial biopharmaceutical public companies.

#### **Research and development**

Research and development expenses for the three months ended September 30, 2017 were \$280,793 with no related expenses for the three months ended September 30, 2016. The expenses are all related to Ovaprene development costs in the current period.

### **Interest income (expense)**

Interest expense increased by \$286,120 to \$296,262 for the three months ended September 30, 2017 from \$10,142 for the three months ended September 30, 2016. The increase was primarily due to \$316,804 expense associated with the beneficial conversion of the Convertible Promissory Notes.

### **Results of Operations — Comparison of Nine Months Ended September 30, 2017 and 2016**

The operations presented in the interim condensed consolidated financial statements and accompanying notes for the nine months ended September 30, 2017 represent the operations of the Company and give effect to the Stock Purchase Transaction. The interim condensed consolidated financial statements and accompanying notes for the nine months ended September 30, 2016 represent the operations of Private Daré, making a comparison between periods difficult.

The following table summarizes Daré's consolidated results for the nine months ended September 30, 2017 and 2016, together with the changes in those items in dollars:

	Nine months ended September 30,		Change
	2017	2016	Dollars
Operating expenses:			
General and administrative	\$ 1,729,338	\$ 119,283	1,610,055
Research and development expenses	312,169	72,666	239,503
License expenses	—	250,000	(250,000)
Total operating expenses	<u>2,041,507</u>	<u>441,949</u>	<u>1,599,558</u>
Loss from operations	(2,041,507)	(441,949)	(1,599,558)
Interest income (expense)	(330,233)	(30,205)	(300,028)
Net Loss	<u>\$ (2,371,740)</u>	<u>\$ (472,154)</u>	<u>(1,899,586)</u>
Other comprehensive loss:			
Foreign currency translation adjustments	\$ (9,774)	\$ —	(9,774)
Comprehensive loss	<u>\$ (2,381,514)</u>	<u>\$ (472,154)</u>	<u>(1,909,360)</u>

### **General and administrative**

General and administrative expenses increased by \$1,610,055 to \$1,729,338 for the nine months ended September 30, 2017 from \$119,283 for the nine months ended September 30, 2016. The increase was primarily due to \$963,380 of legal expense, accounting expense and other expenses incurred in connection with the Stock Purchase Transaction. Daré personnel costs increased \$326,349 due to salaries expense, including bonuses, in the current period with no comparable expense in the same period of the prior year. Following the Stock Purchase Transaction, and based upon the market data presented and recommendation of Radford, the Company's compensation consultant, and upon approval of the Compensation Committee of the Company's Board of Directors, the Company began paying its newly appointed executives compensation at a level in line with market rates for executive officers of early stage, pre-commercial biopharmaceutical public companies.

### **Research and development**

Research and development expenses increased by \$239,503 to \$312,169 for the nine months ended September 30, 2017 from \$72,666 for the nine months ended September 30, 2016. The expenses are primarily due to direct and indirect Ovaprene development costs.

### **License expense**

The license expense of \$250,000 for the nine months ended September 30, 2016 related to fees paid to ADVA-Tec for exclusive option related to the Ovaprene technology. For further discussion of the ADVA-Tec Agreement, see Note 6 of Notes to the Condensed Consolidated Financial Statements.

***Interest income (expense)***

Interest expense increased by \$300,028 to \$330,233 for the nine months ended September 30, 2017 from \$30,205 for the nine months ended September 30, 2016. The increase was primarily due to the \$316,804 expense associated with the beneficial conversion of Convertible Promissory Notes.

***Liquidity and Capital Resources***

As of September 30, 2017, Daré had \$8.53 million in cash and cash equivalents and an accumulated deficit of \$3.1 million. Daré expects that over time, its general and administrative and research and development expenses will increase. As a result, Daré anticipates that it will continue to incur increasing losses in the foreseeable future. Therefore, Daré will need to raise additional capital to fund its operations, which may include the issuance of public and private equity and debt financings, as well as government grants and strategic alliances.



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

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

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 \$6.0 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 intend to cover future operating expenses through cash and cash equivalents on hand and through a combination of equity offerings, debt financings, government or other grant funding, collaborations and strategic alliances. 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 summarizes Daré's cash flows for the periods indicated:

	<b>Nine months ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
Net cash used in operating activities	\$ (1,579,060)	\$ (205,347)
Net cash provided by investing activities	9,918,440	—
Net cash provided by financing activities	155,000	—
Effect of exchange rate changes on cash and cash equivalent	(9,774)	—
Net increase (decrease) in cash	\$ 8,484,606	\$ (205,347)

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

Cash used in operating activities for the nine months ended September 30, 2017 was \$1,579,060. Cash used in operating activities included the net loss of \$2,371,740, decreased by noncash charges of \$6,953 and non-cash interest of \$316,804. A major component reducing operating cash was a \$224,433 increase of prepaid expenses and other current assets, offset by a \$659,223 increase accounts payable and accrued expenses.

Cash used in operating activities for the nine months ended September 30, 2016 was \$205,347. Cash used in operating activities included the net loss of \$472,154, decreased by noncash charges of \$3. A major component reducing operating cash was a \$13,401 decrease in accounts payable and accrued expenses, offset by a \$250,000 decrease in other receivables.

### **Net cash provided by investing activities**

Cash provided by investing activities for the nine months ended September 30, 2017 was \$9.9 million, consisting of cash acquired through the Stock Purchase Transaction. No cash was provided by investing activities for the nine months ended September 30, 2016.

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

Cash provided by financing activities for the nine months ended September 30, 2017 was \$155,000, consisting of proceeds from issuance of Convertible Promissory Notes.

No cash was provided by financing activities for the nine months ended September 30, 2016.

### ***Future Funding Requirements***

We have not generated any revenue to date, and we cannot anticipate if, and when we will generate any revenue. Future product revenue will require us to obtain regulatory approvals in order to sell any products. Revenue from potential strategic partnerships will also require us to advance clinical candidates to meaningful development milestones. At the same time, we expect our expenses to increase in connection with the postcoital clinical study of Ovaprene and any other development activities we may undertake in the future. We also expect to incur additional costs given the requirements of operating as a public company.

As of September 30, 2017, we had cash of approximately \$8.53 million. We will continue to require additional capital to continue to fund our operations, our clinical development activities, expand our product portfolio and if successful, to commercialize any approved products. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition.

We intend to cover our future operating expenses through cash and cash equivalents on hand and through a combination of equity offerings, debt financings, government or other grant funding, collaborations and strategic alliances. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our current stockholders will be diluted.

### ***License and Royalty Agreements***

We signed an agreement to obtain a license from ADVA-Tec (the “ADVA-Tec Agreement”) for the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide that became effective once the initial funding called for by the ADVA-Tec Agreement was secured. ADVA-Tec and its affiliates own issued patents or patent applications covering Ovaprene, and control proprietary trade secrets covering the manufacture of Ovaprene. As of the date of these financial statements, this patent portfolio includes 12 issued patents worldwide, along with eight patent applications, all of which in accordance with the terms of the ADVA-Tec Agreement are exclusively licensed to the Company. We also have a right of first refusal to license these patents and patent applications for purposes of additional indications for Ovaprene. Under the ADVA-Tec Agreement, ADVA-Tec will conduct certain research and development work as necessary to allow us to seek a Premarket Approval (“PMA”) from the FDA, and will supply us with our requirements of Ovaprene for clinical and commercial use on commercially reasonable terms.

Under the ADVA-Tec Agreement, we are required to make payments of up to \$14.6 million in the aggregate to ADVA-Tec based on the achievement of specified development and regulatory milestones, which include the completion of a successful Postcoital Clinical Trial Study (as defined in the ADVA-Tec Agreement); approval by the FDA to commence the Phase 3 pivotal human clinical trial; successful completion of the Phase 3 pivotal human clinical trial; the FDA’s acceptance of the filing of a PMA for Ovaprene; the FDA’s approval of the PMA for Ovaprene; Conformite Europeene 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, we are 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, we are also required to make up to \$20.0 million in the aggregate in commercial milestone payments to ADVA-Tec upon reaching certain worldwide net sales milestones.

We are obligated to use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, such amounts totaling \$5.0 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

The ADVA-Tec license continues on a country-by-country basis until the later of the life of the licensed patents or the Company's last commercial sale of Ovaprene, and the ADVA-Tec Agreement includes customary termination rights for both parties, and provides us 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 we fail 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 Daré and ADVA-Tec, and as may be modified by a joint research committee, where such failure is not caused by events outside of our 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 our reasonable control. In addition, ADVA-Tec may terminate the ADVA-Tec Agreement if we develop or commercialize any non-hormonal ring-based vaginal contraceptive device which is deemed competitive to Ovaprene or, in certain limited circumstances, if we fail to commercialize Ovaprene in certain designated countries within three years of the first commercial sale of Ovaprene. The above description of the ADVA-Tec Agreement is qualified in its entirety by the full text of the agreement, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q.

#### ***Other Contracts***

We enter into contracts in the normal course of business with various third parties for research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and therefore Daré believes that our non-cancelable obligations under these agreements are not material.

#### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk related to changes in interest rates. As of September 30, 2017, Daré had cash on hand of approximately \$8.53 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**

#### ***Evaluation of 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 September 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 nine months ended September 30, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently party to any material pending litigation or other material legal proceeding.

### Item 1A. Risk Factors

There have been no material changes in risk factors from those disclosed in Part II, Item IA. Risk Factors in our interim report on Form 10-Q for the quarterly period ended June 30, 2017.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

- (a) NONE
- (b) NONE
- (c) NONE

### Item 3. Defaults Upon Senior Securities

NONE

### Item 4. Mine Safety Disclosures

NONE

### Item 5. Other Information

- (a) NONE
- (b) NONE

### Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index immediately below.

Exhibit Number	Description of Exhibit	Incorporated by Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of Filing		
3.1	<a href="#">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</a>	10-Q	001-36395	08/14/2017	3.1	
3.2	<a href="#">Second Amended and Restated By-laws, effective July 20, 2017</a>	8-K	001-36395	07/20/2017	3.3	

Exhibit Number	Description of Exhibit	Incorporated by Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of Filing		
10.1	<a href="#">License Agreement dated March 19, 2017, between Daré Bioscience Operations, Inc. and ADVA-Tec, Inc. Δ</a>					X
10.2	<a href="#">Employment Offer Letter by and between Daré Bioscience Operations, Inc. and Sabrina Martucci Johnson dated as of May 31, 2017</a>					X
10.3	<a href="#">Employment Offer Letter by and between Daré Bioscience Operations, Inc. and Lisa Walters-Hoffert dated as of May 31, 2017</a>					X
10.4	<a href="#">Employment Offer Letter by and between Daré Bioscience Operations, Inc. and Mark Walters dated as of May 31, 2017</a>					X
10.5	<a href="#">Employment Agreement by and between Daré Bioscience, Inc. and Sabrina Martucci Johnson dated as of August 15, 2017</a>	8-K	001-36395	08/18/2017	10.1	
10.6	<a href="#">Employment Agreement by and between Daré Bioscience, Inc. and Lisa Walters-Hoffert dated as of August 15, 2017</a>	8-K	001-36395	08/18/2017	10.2	
10.7	<a href="#">Employment Agreement by and between Daré Bioscience, Inc. and Mark Walters dated as of August 15, 2017</a>	8-K	001-36395	08/18/2017	10.3	
31.1	<a href="#">Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</a>					X
31.2	<a href="#">Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended</a>					X
32.1	<a href="#">Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
32.2	<a href="#">Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
101.INS	XBRL Instance Document					X

Exhibit Number	Description of Exhibit	Incorporated by Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of Filing		
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Label Linkbase Document					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X

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

## Signatures

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

Daré Bioscience, Inc.

Date: November 13, 2017

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

Date: November 13, 2017

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



**CONFIDENTIAL TREATMENT REQUESTED  
LICENSE AGREEMENT**

This License Agreement (“**Agreement**”) is made and entered into as of the Effective Date (defined below), by and between DARE Bioscience, Inc. (“**Licensee**”), and ADVA-Tec, Inc., having its principal place of business at 51 Technology Drive, Suite B, Anderson, SC 29625 (“**Licensor**”). Licensor and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

**RECITALS**

- A. Licensor owns or controls certain products and intellectual property rights related to a proprietary medical device currently known as the Ovaprene® product (“**Ovaprene**,” as defined in more detail below).
- B. As of the date of last signature hereto (“**Signature Date**”), Licensee has undertaken diligent and good faith efforts to secure an investment of at least one million two hundred fifty thousand dollars (\$1,250,000) (“**Initial Funding**”) in order to satisfy its obligations under Section 2.7(i) of this Agreement.
- C. Subject to and conditioned upon Licensee’s receipt of Initial Funding by September 15, 2017, Licensor is willing to grant to Licensee, and Licensee desires to obtain, an exclusive license under Licensor’s intellectual property rights to develop and commercialize Licensed Products for the Indication (both defined below) worldwide, on the terms and conditions stated herein.

Now, Therefore, Licensor and Licensee hereby agree as follows:

**AGREEMENT**

**1. DEFINITIONS.**

The following terms, whether used in the singular or plural, shall have the meanings set forth below.

**1.1.** “**Affiliate**” means any individual, corporation, association or other business entity, that directly or indirectly controls, is controlled by or is under common control with a Party, for the duration of such control. As used in this definition of “**Affiliate**,” the term “**control**” means the direct or indirect ownership of more than fifty percent (50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation, association or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise.

**1.2** “**Applicable Law**” means laws, statutes, ordinances, codes, rules and regulations as applicable, to which a Party is subject during the Term, including cGMP, Regulatory Approvals and Pricing Approvals, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement.

**1.3** “**Background Technology**” means all technology owned, licensed or controlled by Licensor and its Affiliates and PMI as of the Effective Date, and all improvements, enhancements and modifications thereof or thereto.

**1.4** “**Budget**” means funding required for the Research Program, as determined by the JRC.

**1.4** “**Calendar Quarter**” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

**1.5** “**COGS**” means Licensor’s cost of goods sold for the Licensed Product (calculated in accordance with United States generally accepted accounting principles and adding Licensor’s costs in administering the

*Portions of this Exhibit, indicated by the mark “[\*\*\*]”, were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Quality Agreement and Supply Agreement) (including without limitation amounts paid by Licensor to CMO for the Licensed Product).

**1.6** “**cGMP**” means current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, ICH Guideline Q7A, or equivalent laws, rules, or regulations of an applicable Regulatory Authority at the time of Manufacture.

**1.7** “**Commercialization**” or “**Commercialize**” means any and all activities directed to the marketing, promotion, distribution, offering for sale, and selling of a Licensed Product, importing and exporting of a Licensed Product for sale, and including interacting with Regulatory Authorities in a country regarding the foregoing after obtaining Regulatory Approval of such Licensed Product in such country, and obtaining pricing and reimbursement approvals from such Regulatory Authorities.

**1.8** “**Commercially Reasonable Efforts**” means, with respect to a Party, those efforts and resources commensurate with the efforts and resources commonly used in the industry in connection with the development or commercialization of medical devices that are of similar status, including with respect to commercial potential, the proprietary position of the product, the regulatory status and approval process, the probable profitability of the applicable product, and other relevant factors such as technical, legal, scientific and medical factors.

**1.9** “**Competing Product**” means non-hormonal ring-based vaginal contraceptive devices.

**1.10** “**Control**” or “**Controlled**” means, with respect to any Know-How, Patent Right, Regulatory Approval or other intellectual property right, the ability to grant the right to access or use such item or a license or sublicense with respect thereto without violating any Applicable Law or breaching the terms of any agreement or other arrangement with any Third Party.

**1.11** “**Contract Year**” means (a) the period beginning on the Effective Date and ending on the first anniversary of the last day of the calendar month in which the Effective Date falls and (b) each succeeding twelve (12) month period thereafter.

**1.12** “**Cover**” and “**Covered**” means, with respect to a Patent Right, where a Valid Claim of such Patent Right would (absent a license thereunder or ownership thereof) be infringed by the Exploitation of the applicable product; *provided, however*, that in determining whether a Valid Claim that is a claim of a pending application would be infringed, it shall be treated as if issued in the form then currently being prosecuted.

**1.13** “**De Facto Exclusivity**” means, with respect to any Licensed Product within any Royalty Country, any given Calendar Quarter during which (i) no Third Party has obtained Regulatory Approval for sale (if required) in such Royalty Country for a Competing Product and (ii) no Third Party has made at least one commercial sale for value of a product that is competitive to the Licensed Product in such Royalty Country within six (6) months prior to or after such Calendar Quarter. Notwithstanding the above, all countries in the Territory without a Valid Claim are deemed to have De Facto Exclusivity unless Licensee can provide verifiable third-party evidence to the contrary.

**1.14** “**Development**” or “**Develop**” means the research, development and regulatory activities relating to obtaining or maintaining Regulatory Approval of a Licensed Product, including preclinical testing, toxicology and pharmacology studies, statistical analysis and report writing, clinical trials, and preparation of applications for Regulatory Approval, but excluding Manufacturing and Commercialization.

**1.15** “**Effective Date**” means the date that Licensee receives the Initial Funding, provided that such date is no later than September 15, 2017 (and for the avoidance of doubt if Licensee does not receive Initial Funding by September 15, 2017, then there is no Effective Date).

**1.16** “**EMA**” means the European Medicines Agency and any successor entity thereto.

**1.17** “**Exploit**” means to Develop, Commercialize, discover, optimize, research, Manufacture, use, offer for sale, sell, import, export or otherwise commercially exploit a product.

**1.18** “**FDA**” means the U.S. Food and Drug Administration and any successor entity thereto.

**1.19** “**First Commercial Sale**” means, with respect to each Licensed Product, the first sale of such Licensed Product by Licensee or its Sublicensee to a Third Party following Regulatory Approval in such country.

**1.20** “**Indication**” means all uses for human contraceptive devices. The Parties may, by written agreement as described in more detail below in Section 2.4, amend the Indication as desired, for example, to include vaginal health as a secondary endpoint.

**1.21** “**Know-How**” means not publicly known ideas, inventions, information, business methods, discoveries, diagrams, plans, concepts, formulas, practices, procedures, processes, methods, knowledge, Trade Secrets, technology, designs, drawings, computer programs, skill, experience, documents, results, clinical and regulatory strategies, test data (including pharmacological, toxicological and clinical data (and including data relating to a mechanism or action, and all assays, models, and biological, chemical, pharmacological, toxicological, clinical and assay results), analytical and quality control data, manufacturing data and descriptions), and legal data, market data, and financial data or descriptions, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable, and all improvements thereto.

**1.22** “**Licensed Product**” means an intravaginal device designed for the Indication wherein the ringed-mesh comprises a composite ring comprising a flexible matrix containing one or more bioactive agent or agents and needed excipients or modulators, which encircles a fluid-permeable mesh material, where the manufacture, use, sale or import of which is Covered by the Licensor Patent Rights and/or the Licensor Know-How.

**1.23** “**Licensor Know-How**” means all Know-How that is (i) Controlled by Licensor and its Affiliates (other than PMI) as of the Effective Date or during the Term that is not publicly known (even though parts thereof may be publicly known); and/or (ii) necessary or useful to Develop, Manufacture and/or Commercialize a Licensed Product. Notwithstanding the above, Know-How Controlled by PMI is excluded from the definition of Licensor Know-How. Know-How Controlled by PMI will only be transferred to Licensee in the context of a Supply Agreement (defined in Section 6.2). Know-How to be transferred shall be limited to the physical properties (*e.g.*, mechanical strength, diameter, degradation profile and the like) of the components of Ovaprene, but not the manufacturing and/or testing methodologies used to produce the fiber and/or the base polymers that make up the components of Ovaprene.

**1.24** “**Licensor Patent Rights**” means the patents and patent applications listed on **Exhibit A** and all Patent Rights relating thereto.

**1.25** “**Licensor Technology**” means Licensor’s rights under Inventions, Licensor Know-How and Licensor Patent Rights.

**1.26** “**Manufacture**” or “**Manufacturing**” means the following activities related to the manufacturing of a Licensed Product by licensor, including any ingredient or component thereof, for Development or for Commercialization, including test method results and stability testing, formulation, process development, scale-up, manufacturing, packaging, in-process and finished product testing results, release of Licensed Product or any component or ingredient thereof and quality assurance activities related to any of the foregoing, all to the extent agreed by the Parties in writing.

**1.27** “**Marketing Authorization**” means all approvals and clearances from the relevant Regulatory Authority that are necessary to market and sell a Licensed Product in any country (including all applicable government-purchaser pricing and governmental reimbursement approvals).

**1.28** “**NDA**” means a New Drug Application (as more fully defined in 21 C.F.R. 314.5 et seq. or its successor regulation) and all amendments and supplements thereto filed with the FDA.

**1.29** “**Net Sales**” means, with respect to a Licensed Product, the aggregate gross invoiced sales prices from the sale of Licensed Products sold by Licensee (but not sold by Sublicensees) in the Royalty Countries during each Calendar Quarter, less the following deductions, actually incurred, paid or accrued by Licensee: (i) normal trade, quantity and cash discounts, rebates, or similar payments actually granted or given to wholesalers or other distributors, buying groups, health care insurance carriers, managed care entities or other institutions, including any government-mandated rebates; (ii) returns, rejections or recalls (due to spoilage, damage, expiration of useful life or otherwise); (iii) reasonable freight, packing, shipping and postage charges; and (iv) customs or excise taxes on the sale of a Licensed Product required by Applicable Law, including import duties, value added, sales and use tax and other taxes (except income taxes) or duties relating to importation, use or sales of a Licensed Product. In the event of any sale or other disposal for value, such as barter or counter-trade, of a Licensed Product, other than an arms'-length transaction for cash, Net Sales shall be calculated as above based on the value of the non-cash consideration received or the fair market price of such Licensed Product in the country of sale or disposal. Sales of Licensed Products between or among Licensee and its Affiliates and Sublicensees for use in conducting clinical trials in order to obtain the Regulatory Approval of such Licensed Products, shall be excluded from the computation of Net Sales and no payments shall be payable on such sales. Also, notwithstanding anything to the contrary above, sales or transfers of a Licensed Product at or below cost for any charitable purposes, compassionate use, named patient sales or free samples shall be excluded from Net Sales calculations. In no event shall any particular amount of deduction identified above be deducted more than once in calculating Net Sales (*i.e.*, no “double counting” of reductions). All discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated between Licensed Products and other products of Licensee and its Affiliates and Sublicensees bundled or sold with such Licensed Products such that Licensed Product does not bear a disproportionate portion of such deductions. In addition, any Sales of Licensed Products for post-market studies shall not be considered to be excluded from the computation of Net Sales, unless such Licensed Product is provided free of charge as part of a required post-market study.

**1.30** “**Ovaprene**” means a non-absorbable silicone-based, non-hormonal (which releases ferrous gluconate and ascorbic acid), ring-based vaginal contraceptive device.

**1.31** “**Patent Rights**” means (i) letters patent (or other equivalent legal instrument), including utility and design patents, and including any term adjustment, extension, substitution, registration, confirmation, reissue, re-examination, or renewal thereof, and supplemental protection certificates, and all equivalents and foreign counterparts of any of the foregoing and (ii) any application for any of the foregoing, including any provisional application, reissue application, re-examination application, continuation application, continued prosecution application, continuation-in-part application, or a divisional application, and all equivalents and foreign counterparts of any of the foregoing.

**1.32** “**Phase 1 Clinical Trial**” means a human clinical trial of a Licensed Product on sufficient numbers of normal volunteers and/or patients that is designed to establish that such Licensed Product is safe for its intended use and to support its continued testing in Phase 2 Clinical Trials. For purposes of this Agreement, ‘initiation’ of a Phase 1 Clinical Trial for a Product means the first use or treatment of such Licensed Product in a human subject in a Phase 1 Clinical Trial.

**1.33** “**Phase 2 Clinical Trial**” means a human clinical trial of a Licensed Product that utilizes the information obtained from one or more previously conducted Phase 1 Clinical Trial(s) that is designed to provide a preliminary determination of safety of such Licensed Product in the target patient population over a range of doses and dose regimens. For purposes of this Agreement, ‘initiation’ of a Phase 2 Clinical Trial for a Product means the first use or treatment of such Product in a human subject in a Phase 2 Clinical Trial.

**1.34** “**Phase 3/Pivotal Clinical Trial**” means a pivotal human clinical trial of a Licensed Product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 C.F.R.

§812 or 21 C.F.R. Part 814, as amended (or its successor regulation), for the purpose of enabling the preparation and submission of an NDA or a PMA or a 510(k) notification.

**1.35** “**PMA**” means a premarket approval filed with the FDA for a medical device as required in 21 C.F.R. Part 814.

**1.36** “**Postcoital Study (“PCT”)**” means a human clinical trial of Licensed Product wherein the number of progressively motile sperm that achieve access into the woman’s mid-cycle cervical mucus within a predetermined period of time post-coitus are tabulated.

**1.37** “**Pricing Approval**” means any and all pricing or reimbursement approvals of any Pricing Authority in any jurisdiction that may be required for Commercialization of Licensed Product in such jurisdiction and/or for reimbursement of Licensed Product by national health insurance (or its local equivalent) or other governmental payors in such jurisdiction.

**1.38** “**Pricing Authority**” means any Regulatory Authority in any jurisdiction whose approval or authorization of pricing or reimbursement is required for Commercialization of Licensed Product in such jurisdiction and/or for reimbursement of Licensed Product by national health insurance (or its local equivalent) or other governmental payors in such jurisdiction.

**1.39** “**Promotional Materials**” means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, intended for use or used by or on behalf of Licensee, any of its Affiliates or Sublicensees, and any of their respective sales forces, sales managers and other sales personnel, in connection with promotion of any Licensed Product, which may include without limitation journal advertisements, sales visual aids, leave-behind items, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites and broadcast advertisements.

**1.40** “**Regulatory Approval**” means any approvals, clearances, licenses, permits, registrations or authorizations by any applicable Regulatory Authority, that are necessary for the Development, Manufacture or Commercialization of a Licensed Product in the Territory. Regulatory Approval includes Marketing Authorizations.

**1.41** “**Regulatory Authority**” means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities, including the FDA and EMA, regulating or otherwise exercising authority with respect to the Development, Manufacture or Commercialization of Licensed Products in the Territory.

**1.42** “**Regulatory Materials**” means any and all regulatory submissions, applications, regulatory reports, safety reports, registrations, filings, approvals and associated master file(s), label(s), labeling, package insert(s) and packaging and associated correspondence required to Develop, Manufacture, market, sell and import Licensed Product.

**1.43** “**Royalty Country**” means each country identified on **Exhibit B**, and “**Royalty Countries**” means all of such countries collectively. The Parties may agree to add Royalty Countries to Exhibit B from time to time based upon expansion of Patent Rights into additional countries.

**1.44** “**Royalty Term**” means, for each Licensed Product in each Royalty Country, on a country-by-country basis, the period of time commencing upon First Commercial Sale of such Licensed Product in such Royalty Country and expiring on the later of (a) the date on which the Development, Manufacture and Commercialization of such Licensed Product in such Royalty Country is no longer Covered by a Valid Claim, or (b) expiration of De Facto Exclusivity in such Royalty Country.

**1.45** “**Sublicensee**” means any person or entity to which Licensee grants a sublicense under the rights granted to Licensee under this Agreement.

**1.46** “**Sublicensee Revenue**” means all revenue, including for example, upfront payments, milestone payments and royalties, received by Licensee from Sublicensees in consideration for the grant of a sublicense under Licensor Technology within Royalty Countries during the Royalty Term, excluding (i) payments for equity or debt securities of Licensee which are unrelated to a sublicense of the Licensed Product; (ii) research or development funding to be applied directly to the research and/or development of Licensed Products, and (iii) amounts paid to Licensee for supplies of Licensed Products or other tangible materials, or that are otherwise paid in reimbursement of costs or expenditures, whether incurred before or after the date of the sublicense agreement. Sublicensee Revenue shall not include amounts received in connection with a merger, consolidation or sale of all or substantially all of the business or assets of Licensee (including the assets of Licensee to which this Agreement relates). To the extent Licensee receives compensation for both a grant of a sublicense of rights to commercialize Licensed Products, and the grant of other rights or licenses or undertaking of other obligations, such compensation will be reasonably apportioned between that amount attributable to the sublicense of Licensor Technology and that amount attributable to the grant of other rights or licenses or undertaking of other obligations, which shall be excluded from Sublicensee Revenue; such apportionment to be reasonably agreed by the Parties.

**1.47** “**Territory**” means worldwide.

**1.48** “**Third Party**” means any person or entity other than Licensor, Licensee, or an Affiliate of either of them.

**1.49** “**Trade Secrets**” means any formula, pattern, device or other information or compilations thereof which is used by a Party in its business which gives that Party an opportunity to obtain an advantage over competitors who do not know or use it, or such other information that qualifies as a “Trade Secret” under Applicable Law.

**1.50** “**Valid Claim**” means a claim of any issued and unexpired patent or patent application within the Licensor Patent Rights that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (b) has not been revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) is not lost through an interference proceeding. Notwithstanding the foregoing, if a claim of a pending patent application within the Licensor Patent Rights in the United States has not issued as a claim of a patent within the five (5) years after the PCT filing date from which such claim takes priority (or the first national filing date if no PCT was filed), such claim shall not be a Valid Claim for the purposes of this Agreement, unless and until such claim issues as a claim of an issued patent (from and after which time the same shall be deemed a Valid Claim subject to the foregoing clauses (a) through (d) above). Further notwithstanding the foregoing, the Parties will negotiate in good faith, on a country-by-country basis, the period during which a claim of a pending patent within the Licensor Patent Rights outside of the United States must issue in order for it to be considered a Valid Claim, which period shall not exceed ten (10) years.

**1.51** “**Additional Definitions.**” Each of the following terms has the meaning set forth in the corresponding section of this Agreement indicated below:

<b>Definition:</b>	<b>Section:</b>
Agreement	Preamble
Alliance Manager	4.1.1
Audited Party	8.11
CMO	6.2
Commercialization Plan	7.2
Confidential Information	11.1
Disputes	14.1
Development Plan	5.1

Effective Date	Preamble
Executive Officer	4.1.4
Export Control Laws	2.6
Licensor	Preamble and 2.5
Licensor Indemnitees	12.1
Executive Officers	14.2
Global Product Marks	7.3.1
Indemnitee	12.3
Indemnitor	12.3
Inventions	9.1
Joint Research Committee or JRC	4.1
Local Product Marks	7.3.1
Losses and Claims	12.1
Licensee	Preamble and 2.5
Licensee Indemnitees	12.2
Licensee Standards	12.1
Negotiated Country	8.4.2
Other Indication	2.4
Party and Parties	Preamble
PMI	2.5
Product Infringement Claim	9.4.1
Product Marks	7.3.1
Quality Agreement	5.6
Recall	5.5
Research Plan	3.2
Research Program	3.1.1
Research Term	3.2
Reverted Product	13.6
ROFN	2.4
ROFN Negotiation Period	2.4
ROFN Notice	2.4
Safety Information	5.7
SDEA	5.7
Second Manufacturing Source	6.3
Sublicensee Revenue Share	8.3
Supply Agreement	6.2
Term	13.1
Terminated Country	13.1
VAT	8.12.2

2. LICENSE.

2.1. **License Grant.** Subject to the terms and conditions of this Agreement (including the terms of Section **Error! Reference source not found.**), Licensor hereby grants to Licensee an exclusive (other than as to Licensor in the case of Development and Manufacturing as set forth herein), sublicensable (in accordance with Section 2.2) license under the Licensor Technology to Develop, use, sell offer for sale, have sold, import and otherwise Commercialize and Exploit Licensed Products for the Indication within the Territory. The foregoing license includes the exclusive right to use data and Regulatory Materials related to the Licensed Product for the Indication within the Territory that are Controlled by Licensor, its Affiliates and PMI (including data from clinical trials) in support of Licensee’s practice of the foregoing exclusive license grant.

2.2. **Right to Sublicense.** Licensee may grant one or more sublicenses under the license granted under Section 2.1, in full or in part, by means of written agreement to one or more Third Parties in which Licensee does not have any equity interest (with the right to sublicense through multiple tiers), *provided, however*, that as a

condition precedent to and requirement of any such sublicense: (a) any such sublicense shall be consistent with and subject to the terms and conditions of this Agreement including granting Licensor the audit rights stated in Section 8.11; and (b) Licensee will continue to be responsible for full performance of its obligations under this Agreement, and will be responsible for all actions of such Sublicensees in connection with such sublicense. Licensee shall provide Licensor a copy of any sublicense agreement within 15 business days of its execution, subject to reasonable redaction except that no redaction shall be made which impinges Licensor's ability to determine that the sublicense complies with this Section.

**2.3. Retained Rights; No Other Rights.** All rights not explicitly licensed to a Party under this Agreement are retained by the Party owning such rights, and no other rights are granted by implication, estoppel or otherwise. Notwithstanding the exclusive license granted to Licensee in Section 2.1, Licensor retains the right under the Licensor Technology to perform its obligations under this Agreement, including to Develop and Manufacture Licensed Products for Licensee as set forth herein, and to practice the Licensor Technology for all uses other than the Indication.

**2.4. Additional Indications.** Licensor represents and warrants to Licensee that, as of the Effective Date, neither Licensor nor its Affiliates nor PMI have directly or indirectly granted any Third Party a right or license to Exploit Licensed Products for any use or any indication other than the Indication (e.g., for treatment, diagnosis or prevention of infections, hormone replacement therapy, short cervix applications, cervical ripening, etc.) (each an "**Other Indication**"). Licensor hereby grants Licensee an exclusive right of first negotiation to obtain an exclusive license to Exploit Licensed Products for each Other Indication within the Territory (each, a "**ROFN**") as further described herein. Licensor shall notify Licensee promptly upon Licensor's or its Affiliate's decision to seek a partner for the research, development and/or commercialization of any Licensed Product for use within any Other Indication ("**ROFN Notice**"). Licensee shall have sixty (60) days from its receipt of the ROFN Notice to notify Licensor if Licensee desires to exercise its ROFN with respect to such Other Indication and upon such notice from Licensee, the Parties will negotiate such rights in good faith for a period of one hundred twenty (120) days (the "**ROFN Negotiation Period**"). If, at the end of the ROFN Negotiation Period, the Parties are unable to reach agreement on such terms, or if Licensee does not notify Licensor of Licensee's interest in such Other Indication during such sixty (60) day period, Licensor shall be free to grant a license or enter into any other arrangement with a Third Party to Exploit Licensed Products for such Other Indication. The terms of any such Third Party arrangement shall not, on the whole, be more favorable to such Third Party than the most favorable terms offered by Licensor to Licensee during the ROFN negotiations. Licensor shall notify Licensee within thirty (30) days of entering into an arrangement with a Third Party for the Exploitation of Licensed Products for each Other Indication and, if requested by Licensee in writing, Licensor's Chief Executive Officer shall certify Licensor's compliance with such favored terms requirement within thirty (30) days of receipt of such request.

**2.5. Affiliates.** Each Party acknowledges and accepts that the other Party may exercise its rights and perform its obligations under this Agreement either directly or through one or more of its Affiliates. In any event each Party will remain responsible for the acts and omissions of its Affiliates, as if such action or omission were taken by the Party itself. Notwithstanding anything in this Agreement to the contrary, Poly-Med, Inc. is not a party to this Agreement and its role is limited to the licensor of technology and a subcontractor to Licensor. With regard to its status as a licensor of technology and a subcontractor to Licensor, Poly-Med, Inc. is referred to as "**PMI.**"

**2.6. Export Control Laws.**

2.6.1. In performing this Agreement, each Party agrees to comply strictly and fully with applicable U.S. export control laws, including the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 et seq.), the Trading With the Enemy Act (50 U.S.C. app. §§ 1 et seq.), the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401 et seq.), International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, and all rules, regulations and executive orders relating to any of the foregoing, including but not limited to the Export Administration Regulations (15 C.F.R. §§



730 et. seq.), and the regulations administered by the Office of Foreign Assets Controls of the United States Department of the Treasury, and all export controls imposed on Licensed Products by any country or organization or nations within whose jurisdiction Licensee operates or does business (collectively, “**Export Control Laws**”). Licensee will not export or permit exportation of the Licensed Product or any related technical data or any direct product of any related technical data, outside of the United States without obtaining any required written permission, license, or approval to do so from the Bureau of Industry and Security of the U.S. Department of Commerce and/or other appropriate governmental agencies of the United States.

2.6.2. Licensee shall not (i) export, reexport, or transfer any Licensed Product to any country that is at the time of export, reexport or transfer subject to an embargo by the U.S. government; (ii) export, reexport, or transfer any Licensed Product to any instrumentality, agent, entity, or individual that is acting on behalf of, or directly or indirectly owned or controlled by, any governmental entity that is subject to an embargo by the U.S. government; (iii) export, reexport or transfer any Licensed Product to a national of a country that is subject to an embargo of the U.S. government; and (iv) engage in any transactions or dealings with any organization, entity, or individual identified on the List of Specially Designated Nationals and Blocked Persons (“SDNs”) or the Foreign Sanctions Evaders List, which are both maintained by the Office of Foreign Assets Control of the U.S. Treasury Department, or the Entity List, Denied Persons List, or Unverified List, which are maintained by the Bureau of Industry and Security of the U.S. Commerce Department; in each case to the extent such export, reexport or transfer violates Applicable Laws. Notwithstanding the above and for the avoidance of doubt, Licensee may export, reexport, or transfer any Licensed Product as permitted by Applicable Law or based upon specific or general licenses allowed by Applicable Law at the export, reexport or transfer of the Licensed Product. The Parties acknowledge that the above prohibitions do change from time to time, and any changes in the above can be discussed by the Joint Steering Committee.

(a) **Obligation to Report.** Either Party will immediately report to the to the Party (i) any concerns, suspicions, or actual knowledge of violations of the Export Control Laws or any other similar applicable export control law in performance of this Agreement, or (ii) if either Party becomes the subject of any formal or informal investigation, prosecution, or government or judicial determination related to a violation of Export Control Laws or any other similar applicable export control law, in performance of this Agreement.

(b) **Obligation to Cooperate.** Each Party will fully cooperate and cause its relevant personnel to cooperate with the other Party in the other Party’s review or investigation in relation to an actual or potential violation of any applicable export law or regulation in performance of this Agreement.

(c) **Termination for Non-Compliance.** Each Party understands and acknowledges that, notwithstanding any provision contained herein,

- (i) an intentional violation of this Section 2.6 by any either Party shall be deemed a material breach of this Agreement and will entitle the other Party to (i) terminate this Agreement immediately upon notice for cause, and (ii) be indemnified for and held harmless against any and all damages, fines, penalties, disgorgements, settlements, determinations, or claims faced by or imposed on the non-breaching Party or any of its representatives to the extent attributable to the material breach of this Section by the breaching Party or any of its respective directors, officers, employees, consultants, agents, sublicensees, subcontractors, distributors, subdistributors or other representatives’ and
- (ii) a non-intentional violation of this Section 2.6 by either Party shall be deemed a non-material breach of this Agreement. Such a breach may be cured by reporting as soon as practicable the basis of the breach to

the regulatory agency responsible for the applicable export control laws. In addition each Party must thereafter cooperate with said agency during any investigation and with any subsequent fines or remediation imposed by said agency.

2.7. **Licensee Investment.** Licensee shall invest in the development of a Licensed Product to support the efforts required for regulatory submissions for the Licensed Product, including product development, pre-clinical and or clinical studies, in accordance with the following minimum annual investment schedule:

- (i) Establishing One Million, Two Hundred and Fifty Thousand Dollars (\$1,250,000) in available funds no later than the Effective Date, to cover activities for the first Contract Year, such amount to be spent in equal installments during each Quarter within such Contract Year;
- (ii) Spending One Million Two Hundred Fifty Thousand Dollars (\$1,250,000) during the second Calendar Year; and
- (iii) Spending Two Million Five Hundred Thousand Dollars (\$2,500,000) during the third Contract Year, and during each subsequent Contract Year through the day a final PMA submission is successfully filed with the FDA or the First Commercial Sale, whichever is earlier.

Amounts spent by Licensee during any Contract Year in excess of the amount required to be spent in such Contract Year shall contribute to Licensee's spend requirements applicable to the subsequent Contract Year(s). The Parties shall confer at least quarterly to assess Licensee's progress towards achieving the foregoing minimum investments and spend. Licensee's demonstration of the investments set forth above must be accompanied by actual investor documents and/or financing documents sufficient to evidence to Licensor the investment set forth above. For the avoidance of doubt, the foregoing dollar amounts need not correspond to amounts payable by Licensee to Licensor as consideration for Licensor's costs and expenses as allocated to Licensor pursuant to the Budget.

### 3. RESEARCH PROGRAM.

#### 3.1. Research Program.

3.1.1. During the Research Term, Licensor will carry out a research program to develop Licensed Products in support of obtaining Regulatory Approvals (the "**Research Program**"). The Research Program will include certain pre-clinical Development activities, manufacturing and manufacturing support, develop manufacturing process adequate for the Commercialization Plan, analytical method development and validation, work needed to establish final product specifications, providing animal and clinical trial supplies, analytical testing for product release, manufacturing process improvements, engineering support, transfer activities to an outside contract manufacturing organization, assembly and support of manufacturing section(s) of CE mark, NDA, PMA, or 510(k) notification for regulatory filings, or other regulatory filing. Licensor will not be responsible for technology support for clinical protocols, the conduct of animal studies, or other work outside the scope of specified work. The Research Program will be carried out by Licensor in accordance with the Research Plan. The objective of the Research Program will be for Licensor to Develop Licensed Products for Licensee to advance into human clinical trials and ultimately to Commercialize.

3.1.2. The Research Program will be conducted by Licensor diligently and in good scientific manner, and in compliance with all applicable good laboratory practices and the terms of this Agreement, intended to achieve efficiently and expeditiously the objectives of the Research Program. Licensor shall comply with all Applicable Laws in the performance of work under this Agreement, and

shall ensure that its Affiliates, PMI and Third Party contractors perform all activities under the Research Program in accordance with this Agreement.

3.1.3. Licensor will maintain laboratories, offices and all other facilities (all of which may be virtual or actual business locations), and will engage sufficient personnel in accordance with the Budget as necessary to carry out its responsibilities under the Research Program pursuant to the Research Plan. The professional skills and expertise levels of such personnel shall be appropriate to the scientific objectives of the Research Program. Licensor shall make its personnel reasonably available at their respective places of employment to consult with Licensee on issues arising during the performance of the Research Program.

3.2. **Research Term.** The Research Program will be carried out from the Effective Date through the day a final PMA submission is successfully filed with the FDA or the First Commercial Sale, whichever is earlier (such period, as may be extended pursuant to this Section 3.2, is the “**Research Term**”). Licensee shall have the option to extend the Research Term for four additional three-month periods. In order to exercise its option to extend the Research Term, Licensee must provide Licensor a written notice exercising Licensee’s option to extend the Research Term at least thirty (30) days prior to the scheduled expiration of the Research Term. For each extension of the Research Term, JRC will prepare an update to the Research Plan which will include an updated Budget.

3.3. **Research Plan.** The Research Program will be carried out by Licensor in accordance with a written research plan prepared and agreed upon by the Parties (the “**Research Plan**”). The purpose of the Research Plan is to detail the responsibilities and activities of Licensor with respect to carrying out the Research Program. The Research Plan will include a description of the specific activities to be performed by Licensor in support of the Research Program, a description of the research objectives, projected timelines for completion of such activities, projected costs for completion of such activities and provisions for the supply of research deliverables including but not limited to test method results, prototypes, test units, and supplies of Licensed Product for clinical Development studies by Licensor to Licensee. The Research Plan will be reviewed quarterly and agreed upon by the JRC at least on a quarterly basis in advance of the performance of activities by Licensor and may be updated and amended from time to time, as the JRC determines, *provided that* if the JRC cannot reach consensus, Licensee shall have final decision making authority so long as such decision is made in good faith, and Licensee does not exercise such final decision making authority in a manner that would require any material increase in costs to Licensor for which Licensee will not reimburse Licensor. For purpose of clarity and notwithstanding anything to the contrary above, as between the Parties, Licensor will be exclusively responsible for executing development activities of the Research Program as directed by the JRC, and Licensee is responsible for all clinical and regulatory matters, pre-clinical animal studies and in vitro sperm testing. With respect specifically to aspects of pharmaceutical product development such as the development of dissolution methods, eluent characterization work, product release characterization work, chemical specifications establishment, assay method development and eluent release optimization, the JRC will either approve Licensor resources to conduct the work, or select external experts/labs to produce the data set to satisfy CDER for regulatory submissions.

3.4. **Research Funding.** As compensation for Licensor’s performance of the Research Program in accordance with the Research Plan during the Research Term, Licensee shall pay all of Licensor’s costs and expenses as allocated in the Budget (and any Third Party and PMI costs and fees will be itemized in the Budget and passed through to Licensee at cost). Licensor will keep complete and accurate copies of the underlying invoices paid by Licensor in relation to amounts payable by Licensee to Licensor in connection with the Research Program generated in the then current calendar year and during the preceding seven (7) calendar years (“**Books**”). Licensee will have the right, once annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to Licensor’s prior written consent (which shall not be unreasonably withheld), review Books in Licensor’s primary place of business upon reasonable written notice (which shall be no less than thirty (30) days’ prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of amounts invoiced to Licensee within the twenty four (24) month period preceding the date of the request for

review. No calendar year will be subject to audit under this Section 3.3 more than once. Licensor will receive a copy of each such report concurrently with receipt by the Licensee. Should such audit certify a discrepancy to the Licensee's detriment, Licensor will, within forty-five (45) days after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy. The Licensee will pay the full cost of the review unless the underpayment of amounts due to the Licensee is certified to be greater than five percent (5%) of the amount due for the entire period being examined, in which case the Licensor will pay the cost charged by such accounting firm for such review. The Budget shall provide Commercially Reasonable dollar amounts to allow completion of the Research Plan during the Research Term, which in no event will be less than that provided in Section 13.5(a).

**3.5. Research Program Records.** Licensor will maintain complete and accurate records of all work conducted in the performance of the Research Program and all of Licensor's results, data, inventions and developments which relate to Ovaprene and are made in the performance of the Research Program. Such records will be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Licensor shall maintain appropriate records sufficient to document the work performed by each of the individuals working in support of the Research Program and the time such individuals spent working in support of the Research Program. Licensor shall provide copies of all requested records within thirty (30) days of such request. In order to protect the Parties' patent rights law in any inventions conceived or reduced to practice during or as a result of the Research Program, Licensor shall require such individuals to record all inventions in standard laboratory notebooks (paper or electronic) or other suitable means that are dated and corroborated by non-inventors on a regular, contemporaneous basis.

**3.6. Disclosure of Results of Research Program.** Licensor will disclose all patent applications that are filed by Licensor, and all patentable inventions, in each case which result from work done under the Research Program and that are not Background Technology. Within thirty (30) days following the end of each Calendar Quarter, Licensor shall provide to the JRC a written report summarizing in reasonable detail the work performed by it under the Research Program and results achieved during the preceding Calendar Quarter. In addition, upon reasonable request by Licensee, Licensor will make presentations to the JRC of its activities related to the Licensed Products to inform Licensee of the details of the work done in the performance of the Research Program, and with respect to use of the Licensed Products for any Other Indication. Upon reasonable request by Licensee, Licensor shall provide Licensee with additional data, results and other information with respect to the work performed by Licensor in the performance of the Research Program. In addition, at Licensee's request, Licensor will transfer (within thirty (30) days of such request) to Licensee all data, results, and information related to testing and studies of Licensed Products (including analytical test results and non-clinical pharmacology and safety data) in the possession of Licensor to the extent such data, results and/or information are necessary or reasonably useful for the Exploitation of Licensed Products.

**3.7. Subcontracting.** Except as may be provided in the Research Plan or as may be specifically permitted in writing by the JRC, or otherwise agreed to in advance in writing by Licensee, Licensor shall not subcontract any of the work for which it is responsible in the performance of the Research Program. In the case of any such permitted subcontracting to a Third Party or Affiliate, such Third Party or Affiliate shall have entered into a written agreement with Licensor that includes terms and conditions protecting and limiting use and disclosure of Confidential Information, and addressing ownership of intellectual property rights, at least to the same extent as under this Agreement; *provided* that the term of such Third Party's or Affiliate's obligations regarding the use and disclosure of Confidential Information shall be as long as can be reasonably negotiated with such Third Party or Affiliate, but in any event no less than seven (7) years after the date of disclosure to the Third Party or Affiliate. Notwithstanding the above, Licensor shall have the right to subcontract work to PMI for any purpose, and to Third Parties for Quality Assurance and Quality Control analysis, sterilization and /or packaging of Licensed Product upon notice to but without the consent of Licensee. In any and all such events Licensor is liable and responsible for compliance by such Third Party, PMI and Affiliates with the applicable terms and conditions of this Agreement in the same way and to the same extent as Licensor, and Licensor will be responsible for any Third Party's, PMI's and Affiliates' compliance with this Agreement and that such Third Party, PMI and Affiliate complies with all Regulatory requirements relevant to the performance of such activities.

**3.8. Information Transfer to Licensee.** Without limiting the licenses and other rights and obligations under this Agreement, subject to the provisions of Section 1.23, upon request by Licensee, Licensor shall, on an ongoing basis during the Term, deliver, and cause its Affiliates to deliver, to Licensee, all Licensor Know-How in Licensor's possession for purposes of supporting the Development and Commercialization of Licensed Products by Licensee. In addition, subject to the provisions of Section 1.23, Licensor shall promptly disclose to Licensee's Alliance Manager any inventions under the Research Plan for which Licensor has determined it desires to seek Patent Rights. Licensor shall provide reasonable consultation and assistance for the purpose of transferring to Licensee the Licensor Know-How to the extent reasonably necessary or useful for Licensee to Develop and Commercialize Licensed Products in the Indication

**4. GOVERNANCE.**

**4.1. Overview.** Within fifteen days (15) days after the Effective Date, the Parties shall establish a joint research committee (the "**Joint Research Committee**" or the "**JRC**") which shall oversee and manage Licensor's performance of the Research Program.

**4.1.1. Alliance Managers.** Each Party shall appoint one representative who possesses a general understanding of development, regulatory, manufacturing and commercialization matters to act as its respective alliance manager(s) for this relationship (an "**Alliance Manager**"). Each Party may replace its respective Alliance Manager at any time upon written notice to the other in accordance with this Agreement. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for:

- (a) providing a primary single point of communication responsible for the flow of communication and for seeking consensus both within the respective Party's organization and together with the other Party regarding key strategy and plan issues;
- (b) ensuring awareness of the governance procedures and rules set forth herein and monitoring compliance therewith;
- (c) identifying and raising disputes to the JRC for discussion in a timely manner; and
- (d) planning and coordinating internal and external communications in accordance with the terms of this Agreement.

The Alliance Managers may attend all JRC meetings, and may bring any matter to the attention of the JRC where such Alliance Manager reasonably believes that such matter requires attention of the JRC. After the Effective Date each Party shall appoint and notify the other Party of the identity of their representative to act as its Alliance Manager as of the Effective Date.

**4.1.2. Joint Research Committee.**

- (a) **Composition.** The Joint research Committee shall be comprised of two (2) named representatives for each Party (or such other number as the Parties may agree), including each Party's Alliance Manager. The JRC will be led by the Licensee's Alliance Manager. Each Party may replace one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change.
- (b) **Role of the JRC.** The JRC will be responsible for (i) the overall oversight and management of the Research Program, and for approving changes and updates to the Research Plan, (ii) the monitoring, reviewing and recording of the progress of the Research Program, (iii) setting, and monitoring the spending against, the Research Funding and the Budget, and (iv) facilitating the prosecution of the Licensor Patent Rights in accordance with Article 9. As needed, the JRC shall establish subcommittees and working groups that will

report to the JRC to further the objectives of the Research Program. The JRC will keep minutes of JRC meetings that record all decisions and all actions recommended or taken in reasonable detail, and perform any and all tasks and responsibilities that are expressly attributed to the JRC under this Agreement.

(c) **Frequency of Meetings.** The JRC shall meet at least once per quarter or more or less often as otherwise agreed by the Parties, and such meetings may be conducted by telephone, videoconference or in person as determined by the co-chairs; provided that no less than two (2) meetings during each calendar year shall be conducted in person (with each Party's travel costs and expenses to be borne by the respective Party). Each Party may also call for special meetings of the JRC with reasonable prior written notice (it being agreed that at least five (5) business days shall constitute reasonable notice) to resolve particular matters requested by such Party and within the decision-making responsibility of the JRC. Each co-chair shall ensure that its JRC members receive adequate notice of such meetings. Drafts of the minutes shall be prepared by Licensee and circulated to the members of the JRC by the Licensor Alliance Manager within twenty (20) days after the meeting. Each member of the JRC may circulate comments on the draft minutes.

4.1.3. **Information.** Each Party shall provide the JRC such information as required under the Research Plan or as reasonably requested by the other Party and reasonably available, relating to the progress of the goals or performance of activities under each of the Research Plan.

4.1.4. **Decisions.** Other than as set forth herein, in order to make any decision required of it hereunder, the JRC must have present (in person, by videoconference or telephonically) at least the co-chair of each Party (or his/her designee for such meeting). Decisions of the JRC shall be by consensus, with each Party having one (1) vote. If the JRC cannot reach consensus or a dispute arises which cannot be resolved within the JRC within fifteen (15) days, the co-chair of either Party may cause such dispute to be referred to the Chief Executive Officer of Licensee, and President of Licensor (each an "**Executive Officer**") for resolution within thirty (30) days. If consensus cannot be reached with respect to a decision after a meeting of the Executive Officers, then the decision shall be made by Licensee's Executive Officer in all matters; provided that such decision is made in good faith, and such Executive Officer may not exercise his or her final decision making authority to modify Licensor's contractual obligations, or to materially modify Licensor's Research Plan commitments, including that would increase any Budget under the Research Plan for which Licensee would not be responsible.

4.1.5. **Authority.** The JRC and any subcommittee shall have only the powers assigned expressly to it in this Article 4 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JRC or subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

4.2. **Discontinuation of JRC.** The JRC shall continue to exist until the end of the Research Term, at which time it will disband.

## 5. DEVELOPMENT AND REGULATORY MATTERS.

5.1. **Development Plan.** Licensee shall be responsible for, and shall use Commercially Reasonable Efforts to, perform the Development activities set forth in the Development Plan attached hereto as **Exhibit D** (the "**Development Plan**") in order to obtain Regulatory Approval to market the Licensed Products within the Territory for the Indication. Failure to achieve, in whole or in part, the goals of the Development Plan shall not in itself be deemed a failure to meet the obligations under the Development Plan or this Section 5.1. Licensee may request that Licensor provide additional services in support of Licensee's performance of the Development Plan, in which case the Parties will negotiate and enter into a separate development services agreement under commercially reasonable terms.

5.2. **Regulatory Matters.** Licensee shall be solely responsible for seeking and obtaining Regulatory Approval for the Licensed Products from Regulatory Authorities in the Territory, including the preparation, submission and maintenance of Regulatory Materials to Regulatory Authorities and any interactions with Regulatory Authorities. Without limiting the generality of the foregoing, Licensee shall have sole responsibility and decision-making authority with respect to the content of any regulatory filing or dossier, pharmacovigilance reporting, labeling, safety, and the decision to file or withdraw any Marketing Authorization or to cease or suspend any clinical trial. Licensee will own all regulatory materials for Licensed Products and all such regulatory materials shall be submitted in the name of Licensee (or its Affiliate or Sublicensee, as applicable), and Commercialization of Licensed Products shall be conducted under Marketing Authorizations that will be owned by Licensee or its Affiliate or Sublicensee, as applicable. Licensee (or its Affiliate or Sublicensee, as applicable), will provide a copy to Licensor of all submissions and communications with Regulatory Authorities and an irrevocable right to reference these files. Licensor's right to reference must be a component of the submission to the regulatory authority at the time of submission. Licensee will transfer all registrations and approvals to Licensor upon termination of this Agreement.

5.3. **Cooperation.** Each Party shall provide the other Party with such cooperation and assistance as may reasonably be requested with respect to Regulatory Approvals, Regulatory Materials and interactions and communications with the Regulatory Authorities in respect of Licensed Products within the Territory.

5.4. **Threatened Agency Action.** Each Party shall promptly notify the other Party's regulatory affairs department of any information that such Party receives regarding any threatened or pending action by any Regulatory Authority, or any potential request by a Regulatory Authority, that may affect the proposed labeling or approved labeling for a Licensed Product or may affect the continued Commercialization of a Licensed Product. Upon receipt of any such information, each Party shall consider in good faith the other Party's comments with respect to the appropriate action to be taken; *provided, however*, that nothing herein shall be construed to prevent a Party from complying with its obligations under the SDEA or with such Party's regulatory reporting obligations under Applicable Laws.

5.5. **Recalls.** Each Party shall promptly notify the other Party in writing if it determines that any event, incident or circumstance has occurred that may result in the need for a "recall", "field correction" or "market withdrawal" (as such terms are defined in Title 21 of the Code of Federal Regulations, Section 7.3 or a similar regulation of any governmental authority and further defined in relevant guidelines or guidance from a Regulatory Authority) of a Licensed Product (a "**Recall**"). Licensee shall have the sole right to determine whether or not to initiate a Recall. If at any time (i) any Regulatory Authority in the Territory issues a request, directive or order for a Recall of a Licensed Product, (ii) a court of competent jurisdiction orders a Recall of a Licensed Product, or (iii) Licensee determines to initiate a Recall, then the Parties shall establish and coordinate a strategy pursuant to which Licensee will engage in discussions with the Regulatory Authorities with respect to the Recall, and will keep Licensor informed of the progress. The Parties shall determine the allocation of out of pocket costs incurred in performing a Recall consistent with the Parties' responsibilities and liabilities relating thereto.

5.6. **Quality Agreement.** Within ninety (90) days of the Effective Date, the Parties shall enter into a written quality assurance agreement setting forth the specific responsibilities, procedures and guidelines for batch release, quality control testing, quality assurance review, acceptance testing and other quality-related aspects of the manufacture and release of Licensed Products by Licensor or a CMO (as such agreement may be amended from time to time by mutual written agreement of the Parties, the "**Quality Agreement**"). Each Party (or the CMO, as applicable) agrees to perform the responsibilities assigned to such party under the Quality Agreement in accordance with the terms and conditions of the Quality Agreement. In case of any conflict between the provisions of this Agreement and those of the Quality Agreement, the Quality Agreement shall prevail as to any quality-related matter, and this Agreement shall prevail as to all other matters.

5.7. **Pharmacovigilance and Safety Monitoring Activities.** Within ninety (90) days of the Effective Date, the Parties shall enter into a Safety Data Exchange Agreement ("**SDEA**"), governing the Parties' respective

responsibilities with respect to adverse events, device malfunctions, complaints and other safety-related matters with respect to the Licensed Products. The SDEA shall set forth specific details regarding the exchange and management of information relating to adverse events related to the use of Licensed Products, and shall, among other terms, specify (i) which Party shall be responsible for adverse event, malfunction and Licensed Products complaint reporting to specific Regulatory Authorities, consistent with Applicable Law and ownership of Regulatory Approvals, (ii) that each Party shall maintain a record noting in reasonable detail any and all complaints and notices of safety concerns and adverse events it receives with respect to Licensed Product (collectively the “**Safety Information**”) and (iii) each Party shall provide to the other Party or its designee all Safety Information in a format and in a form agreed to by the Parties in SDEA to enable the other Party to comply with Applicable Law (with such Safety Information being provided, in any event within two (2) business days after such Safety Information is first received if such Safety Information concerns a matter with the potential to adversely affect patient safety, and within seven (7) business days after such receipt otherwise). Notwithstanding anything to the contrary, within the context of the SDEA Licensee shall be responsible for investigating evaluating, and reporting all reportable adverse events or malfunctions to the relevant Regulatory Authorities.

**5.8. Licensee’s Rights of Reference.** Subject to the rules of the relevant Regulatory Authority, Licensor hereby grants to Licensee a revocable right of reference to any Regulatory Approval Controlled by Licensor (including any Marketing Authorization approved by the relevant Regulatory Authority) relating to the Licensed Products (including, without limitation, the right to rely upon, access, inspect, copy and otherwise use all information and data included in or used to support any such Regulatory Approval), solely for Licensee’s and Sublicensees’ use in Development, Manufacturing (subject to Article 6) and Commercialization of Licensed Products in the Territory during the Term in accordance with this Agreement. Licensor shall take such actions as may be reasonably requested by Licensee to give effect to the intent of this Section 5.8 and to give Licensee the benefit of Licensor’s Regulatory Approvals as provided in this Section 5.8. Such actions may include, without limitation, providing a signed statement upon which Licensee may rely, and that the Regulatory Authority may access, in support of the Licensee’s application for Regulatory Approval, and providing any underlying raw data or information submitted by Licensor to a Regulatory Authority, Regulatory Approval, or other regulatory documentation Controlled by Licensor or its Affiliates that relates to any Licensed Product, or entering into one or more distribution agreements or taking other reasonable actions to enable Licensee to register as a distributor with the applicable Regulatory Authority.

**6. MANUFACTURING AND SUPPLY.**

**6.1. General.** Licensor shall be responsible for all activities related to process development and scale up manufacturing, in accordance with the Budget, for each Licensed Product, all as the Parties may agree in writing.

**6.2. Manufacturing.** Subject to Section 6.3, Licensor shall supply, either through itself or a Third Party contract manufacturing organization (“**CMO**”), to Licensee, such quantities of Licensed Products necessary for Licensee’s Development and Commercialization of Licensed Products in the Territory at a price equal to Licensor’s COGS plus a commercially reasonable margin as the Parties agree in writing, and in accordance with the product specifications and requirements set forth in the Supply Agreement and the Quality Agreement. Subject to the foregoing and to Section 6.3, Licensee shall not obtain Licensed Products from any source other than Licensor (or with Licensor’s permission, Licensor’s CMO) without the approval of Licensor, which shall not be unreasonably withheld subject to the understanding that the license from PMI to Licensor requires that PMI be the exclusive manufacturer of any Licensed Product and is a condition of this License Agreement. The parties shall negotiate and enter into one or more supply agreements on reasonable and customary terms, consistent with the terms herein, governing the supply of Licensed Products from Licensor or CMO to Licensee (including any quality agreement, each a “**Supply Agreement**”).

**6.3. Secondary Manufacturing Source.** Commencing upon FDA approval of the PMA or NDA, and in accordance with the terms of the Supply Agreement and the Quality Agreement, Licensor shall have qualified



and keep qualified an additional manufacturing source (a “**Second Manufacturing Source**”) in accordance with the terms of the Supply Agreement. Licensor shall ensure that the Second Manufacturing Source shall be ready and able to supply Licensed Products to Licensee in accordance with the terms of the Supply Agreement and the Quality Agreement, and Licensor shall engage the Second Manufacturing Source to manufacture and supply Licensed Products for Licensee should Licensor and CMO be unable to comply with the Supply Agreement and the Quality Agreement. The Second Manufacturing Source must be a second facility operated by Licensor’s CMO or Third Party CMO with quality and reliability in manufacturing comparable to Licensor’s CMO, and such Second Manufacturing Source must be approved by or registered with the FDA or other relevant regulatory authorities such that Licensed Products manufactured by the Second Manufacturing Source may be lawfully sold by Licensee, its Affiliates and Sublicensees. If the Licensor is unable or unwilling to provide a Second Manufacturing Source, then the Licensee shall have the right to identify a third party to provide this capability and to require Licensor to transfer Licensor Know-How to the third party (under the terms and conditions of this Agreement), and Licensor shall promptly comply with such requirement.

## 7. COMMERCIALIZATION.

**7.1. Generally.** Except as set forth in Section 7.3, Licensee shall be solely responsible for the Commercialization of Licensed Products in the Territory, at its own expense. Licensee’s Commercialization responsibilities in the Territory shall include the following activities: (i) developing and executing a plan for Commercialization activities for the Licensed Products; (ii) negotiating with applicable Regulatory Authorities regarding the price and reimbursement status of Licensed Product and obtaining pricing and reimbursement approvals from Regulatory Authorities; (iii) marketing and promotion, including the preparation of packaging and promotional materials for Licensed Products; (iv) medical affairs; (v) booking sales and distribution and performance of related services; (vi) handling all aspects of order processing, invoicing and collection, inventory and receivables; (vii) providing customer support, including handling medical queries; and (viii) conforming its practices and procedures to Applicable Law relating to the marketing, detailing and promotion of Licensed Product in the Territory.

**7.2. Commercialization Plan.** No later than twelve (12) months prior to the anticipated First Commercial Sale (or earlier, if necessary to secure pricing or reimbursement approvals in such country) for each Licensed Product, Licensee shall provide to Licensor the following plan (each, a “**Commercialization Plan**”): (i) a reasonably detailed and written plan for Commercialization of such Licensed Product, (ii) a rolling five (5)-year budget for such activities for such Licensed Product in the Territory, and (iii) a non-binding, rolling sales projection for the next five (5) years for such Licensed Product. Each such Commercialization Plan may be updated by Licensee and submitted to Licensor from time to time. Failure to achieve, in whole or in part, the goals of the Commercialization Plan shall not in itself be deemed a failure to meet the obligations under this Section.

### 7.3. Trademarks; Packaging; Promotional Materials.

**7.3.1. Trademarks.** Licensee shall determine and approve all trademarks or trade names for the Licensed Products for the Indication within the Territory (the “**Product Marks**”), subject to Licensor’s final decision-making authority for the Global Product Marks (as defined below) and Licensee’s final decision-making authority for the Local Product Marks (as defined below). Licensor shall be responsible for (i) registering and owning the Product Marks used globally and throughout the Territory (with the exception of any Local Product Marks used only in a particular country within the Territory) (the “**Global Product Marks**”), (ii) registering, prosecuting and enforcing the Global Product Marks in the Territory, (iii) the accrual of goodwill as a result of the use of the Global Product Marks, (iv) any branding guidelines applicable to the use of the Global Product Marks and (v) the investigation and defense of any infringement or threatened infringement relating thereto. The Parties anticipate that the Licensed Products will be Commercialized throughout the Territory under the Global Product Mark of “*Ovaprene*”. Licensee shall be responsible for (a) registering and owning the Product Marks used locally only in a particular country in the Territory (the “**Local Product Marks**”), (b) registering,

prosecuting and enforcing the Local Product Marks in any country in the Territory (c) the accrual of goodwill as a result of the use of the Local Product Marks, (d) any branding guidelines applicable to the use of the Local Product Marks and (e) the investigation and defense of any infringement or threatened infringement relating thereto. For purpose merely of clarity, Licensor reserves the right to require the use of Licensor's trademark "Ovaprene®" on any Licensed Product.

7.3.2. **Trademark Licenses.** If Licensor has rights to a Global Product Mark, Licensor hereby grants and shall grant to Licensee an exclusive, royalty-free license, with the right to sublicense, to use the Global Product Mark in connection with the Commercialization of Licensed Products in the Territory, subject to the terms and conditions of this Agreement. Each Party acknowledges (i) that Licensor has sole and exclusive rights to the Global Product Marks and (ii) that Licensee has sole and exclusive ownership of all rights, title and interests in and to the Local Products Marks (including, without limitation, all registrations and applications therefor). Neither Party will register in its own name any Product Mark owned by the other Party, corporate name, domain name, social media account or other source identifier containing such Product Mark or any word or mark that is confusingly similar to such Product Mark. All use of a Global Product Mark and all goodwill and benefit arising from such use will inure to the sole and exclusive benefit of Licensor and all use of a Local Product Mark and all goodwill and benefit arising from such use will inure to the sole and exclusive benefit of Licensee. Each Party will cooperate with the other Party in the execution, filing and prosecution of any trademark applications in connection with a Product Mark. Licensee shall assure at all times that the quality of the Licensed Products is of a standard of quality consistent with pharmaceutical industry standards. Licensee shall assure at all times that Licensed Products are sourced, manufactured and labelled in accordance with Applicable Law. Licensee shall place and display the Global Product Marks on and in connection with the Licensed Products only in such form and manner as are specifically approved in writing in advance by Licensor. Except as otherwise expressly provided in this Agreement, neither Party is granted any license under, and shall not use, any trademarks of the other Party in connection with the Licensed Products.

7.3.3. **Packaging and Promotional Materials.** Licensee shall be responsible for the preparation of the design of all final packaging (non-commercial and commercial) and promotional materials for use in Commercializing Licensed Products in the Territory.

8. **FINANCIAL TERMS.**

8.1. **License Fee.** Left intentionally blank.

8.2. **Development, Regulatory and Commercial Milestone Payments.**

8.2.1. **Development and Regulatory Milestones.** For the first Licensed Product that is Commercialized hereunder (and for no other Licensed Product), Licensee shall promptly notify Licensor following the first achievement of each of the corresponding milestone events set forth below by such Licensed Product. Following receipt of such notice, Licensor shall invoice Licensee for, and Licensee shall pay to Licensor the following corresponding one-time milestone payment within thirty (30) days of its receipt of such invoice:

<u>Milestone Event</u>	<u>Milestone Payment</u>

<p>1.</p>	<p>Successful Postcoital Study.</p>	<p>\$[***] will be payable upon confirmation that 100% of the PCT participants have fewer than 5 progressively motile sperm in the cervical mucus per high power field (and such metric is considered indicative of minimally acceptable barrier function).</p> <p>\$[***] will be payable upon confirmation that 100% of the PCT participants have zero progressively motile sperm in the cervical mucus per high power field.</p> <p>\$[***] will be payable upon confirmation that the Licensed Product is “well-tolerated” and resulted in no serious adverse events or malfunctions. For clarity, “well-tolerated” means no significant change in genital flora, no significant (reportable) discomfort, no bleeding, no pain or other safety concern, no colposcopic abnormalities related to the Licensed Product, and at least 80% of test subjects report the Licensed Product is considered acceptable to sexually active women and their partners.</p>
<p>2.</p>	<p>Approval by the US Food and Drug Administration to commence Phase 3/Pivotal Clinical Trial</p>	<p>\$[***]</p>
<p>3.</p>	<p>Completion of successful Phase 3/Pivotal Clinical Trial, where “completion” is defined as completion of minimal number of subjects, total cycles, and successive cycles per subject, all as required by the FDA for registration in the United States.</p> <p>The proposed primary endpoint for the Phase 3/Pivotal Clinical Trial is to estimate the risk of pregnancy among users of the Product over 6 months of typical use. The secondary endpoints will clinically evaluate the safety of the Product during the same time period.</p>	<p>\$[***] will be payable upon clinical trial effectiveness rate of 68-80% in typical use as a result of the clinical trial, which is comparable to the category of barrier methods.</p> <p>\$[***] will be payable upon clinical trial effectiveness rate of between 80.1-86% in typical use, which is comparable to the category of barrier methods with spermicide use (double method approach).</p> <p>\$[***] will be payable upon clinical trial effectiveness rate in typical use of between 86.1 and 89.9%, which is greater than all other barrier methods, including use with spermicides.</p> <p>\$[***] will be payable upon clinical trial effectiveness rate in typical use of greater than 90% as a result of the clinical trial, which is comparable to the US approved prescribing information of the NuvaRing or its generic equivalent.</p> <p>\$[***] will be payable upon confirmation that Licensed Product is “well-tolerated” and resulted in no serious adverse events or malfunctions. For clarity, “well-tolerated” means no significant change in genital flora, no significant (reportable) discomfort, no bleeding, no pain or other safety concern, no colposcopic abnormalities related to the Licensed Product, and at least 80% of test subjects report the Licensed Product is considered acceptable to sexually active women and their partners, at the 6 month time point.</p>

4.	The FDA accepts the filing of a PMA	\$[***]
5.	The FDA approves the PMA	\$[***]
6.	CE Marking of the Licensed Product or filing in at least three of the following: Germany, France, Italy, Spain, United Kingdom.	\$[***]
7.	Regulatory Approval by EMA or Regulatory Approval in at least three of the following: Germany, France, Italy, Spain, United Kingdom.	\$[***]
8.	Regulatory Approval in Japan	\$[***]

For clarity, each Milestone Payment is payable only once and the maximum amount payable under this Section 8.2.1 is Fourteen million and six-hundred thousand dollars (\$14.6 million).

8.2.2. **Commercial Milestone Payments.** Licensee shall promptly notify Licensor in writing following the first achievement of the corresponding commercial milestone events set forth below. Following receipt of such notice, Licensor shall invoice Licensee for, and Licensee shall pay the following one-time, non-refundable, non-creditable milestone payments within thirty (30) days of its receipt of such invoice:

Milestone Event	Milestone Payment
Worldwide Net Sales reach \$[***]	\$[***]
Worldwide Net Sales reach \$[***]	\$[***]

8.3. **Sublicensee Revenue.** In the event of a Sublicense, Licensee shall pay Licensor [\*\*\*] percent ([\*\*\*]%) of Sublicensee Revenue received by Licensee during the Royalty Term in lieu of the Royalty Rate outlined in 8.4 (“**Sublicensee Revenue Share**”) *provided, however, (i) for Sublicensee Revenue received by Licensee from Sublicensees that represents an upfront payment or license fee due on or around the effective date of the sublicense, then the Sublicensee Revenue Share for such Sublicensee shall be lowered to [\*\*\*] percent ([\*\*\*]%) of the Sublicensee Revenue received by Licensee from such Sublicensee prior to the First Commercial Sale (but shall be [\*\*\*] percent ([\*\*\*]%) of Sublicensee Revenue received from such Sublicensee thereafter), and (ii) Sublicensee Revenue received by Licensee for a Sublicensee’s achievement a milestone event described in Section 8.2 shall not, only for purposes of calculating the associated Sublicensee Revenue Share, exceed the amount payable by Licensee for achievement of such milestone event as required in Section 8.2 (even if Licensee receives more than this amount from a Sublicensee).*

**8.4. Royalties.**

8.4.1. **Royalty Rate.** Licensee shall pay to Licensor royalties on annual Net Sales of Licensed Products for each calendar year during the Royalty Term as set forth in the table below. Such annual Net Sales for Licensed Products shall be aggregated for all Licensed Products in order to

determine the royalty rate applicable to all Licensed Products sold during the corresponding calendar year.

Aggregate Annual (i.e. within a calendar year) Net Sales Within the Royalty Countries	Royalty Rate
Net Sales less than or equal to \$[***]	[***]%
Portion of aggregate annual Net Sales greater than \$[***] and less than or equal to \$[***]	[***]%
Portion of aggregate annual Net Sales greater than \$[***] and less than or equal to \$[***]	[***]%
Portion of aggregate annual Net Sales greater than \$[***]	[***]%

For clarity, only one royalty shall be due to Licensor with respect to the same unit of a Licensed Product. For clarity, Licensee shall not owe royalties on Licensed Products sold in a Royalty Country after expiration of the Royalty Term for such Licensed Product in such Royalty Country. Upon the expiration of the Royalty Term with respect to a Licensed Product in a Royalty Country, Licensee shall have a fully-paid-up perpetual license under Section 2.1.

#### 8.4.2. Royalty Reductions.

(a) **De Facto Exclusivity.** On a Royalty Country-by-Royalty Country and Licensed Product-by-Licensed Product basis, if Exploitation of a Licensed Product is not Covered by a Valid Claim in such Royalty Country, but if there is De Facto Exclusivity in such Royalty Country, then the royalty rates set forth in Section 8.4.1 with respect to Net Sales for such Licensed Product in such Royalty Country shall be reduced by [\*\*\*] percent ([\*\*\*]%) of what would otherwise have been due in the absence of such reduction.

(b) **Third-Party Intellectual Property.** If Licensee obtains a license from a Third Party under intellectual property that, in Licensee's reasonable judgment, is necessary or useful for the Exploitation of a Licensed Product within a Royalty Country, then Licensee may credit [\*\*\*] percent ([\*\*\*]%) of the royalties, milestones or other payments that Licensee actually pays to such Third Party for the Exploitation of such Licensed Product in such Royalty Country during a Calendar Quarter against royalties otherwise payable by Licensee to Licensor under Section 8.4.1 for such Licensed Product in such Royalty Country in such Calendar Quarter, provided, however, that under no circumstances shall any royalty payment to Licensor be reduced as a result of this Section 8.4.1(b) to less than [\*\*\*] percent ([\*\*\*]%) of what would otherwise have been due in the absence of such reduction.

8.4.3. **Countries For Which a Royalty Rate and Commercialization Plan Must be Negotiated.** With the exception of Developing World Countries, which means countries listed in Exhibit F, for which royalties are never payable, Licensee may not Commercialize a Licensed Product in a country that is not a Royalty Country unless and until the Parties agree on a royalty rate and Commercialization Plan applicable to such country (hereinafter a "**Negotiated Country**"). More specifically, no later than six (6) months after receiving either US or EU regulatory approval (whichever is earlier) for a Licensed Product, if Licensee wishes to Commercialize such Licensed Product in a Negotiated Country, Licensee shall propose a royalty rate and a Commercialization Plan of such Licensed Product (including a binding timeline for regulatory submissions and good faith estimates of commercialization) for such Negotiated Country, in which case Licensor will respond to and negotiate such proposal diligently and in good faith. Upon the Parties' written agreement as to a royalty rate for any such country, Licensee may Commercialize Licensed Products in such country. The royalty rate applicable to such country shall be set such

that Licensee's cost of goods sold for the Licensed Product (calculated in accordance with United States generally accepted accounting principles) (which costs include any transfer price plus royalty amounts payable by Licensee to Licensor in respect of such Licensed Products) in such country shall not exceed [\*\*\*] percent ([\*\*\*]%) of the sales price for such Product in such country, and in any case such royalty rate shall not exceed the corresponding royalty rate identified in Section 8.4 above. If the Licensee does not propose a Commercialization plan and royalty rate within said six (6) months, or, if, despite their diligent and good faith efforts, the Parties fail to agree in writing upon a royalty rate for each country in the Negotiated Countries within 120 days of the proposal from Licensee, then all such countries for which an agreement could not be reached shall be excluded from the definition of Territory set forth in Section 1.46 (each an "**Excluded Country**"). For any Excluded Country, if any Third Party or any Affiliate of Licensor wishes to commercialize a Licensed Product in such Excluded Country, Licensor may not permit such person or entity to commercialize a Licensed Product in such Excluded Country without first offering Licensee the rights to do so under terms that are, on a whole, at least as favorable to Licensee as the most favorable terms offered by Licensor to such person or entity, and allowing Licensee thirty (30) days to accept or reject such offer.

**8.5. Reports and Payments.** On a Licensed Product-by- Licensed Product basis, after the First Commercial Sale of the first Licensed Product and until expiration of the last applicable Royalty Term, Licensee shall prepare and deliver to Licensor royalty reports of the sale of Licensed Products by Licensee and of Sublicensee Revenue for each Calendar Quarter within sixty (60) days of the end of each such Calendar Quarter specifying (1) all Sublicensee Revenue received during such Calendar Quarter; and (2) in the aggregate and on a Licensed Product-by-Licensed Product basis: (a) total gross amounts for Licensed Products sold or otherwise disposed of by Licensee; (b) amounts deducted in accordance with the definition of Net Sales from gross amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable. Royalties and Sublicensee Revenue will be payable on a quarterly basis and any such payments shall be made within sixty (60) days after the end of the Calendar Quarter during which the applicable Net Sales occurred or Sublicensee Revenue was received.

**8.6. Mutual Convenience of the Parties.** The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts required hereunder.

**8.7. Late Payments.** In the event that any payment due hereunder is not made when due, the payment shall accrue interest from the date due at the rate of 1.5% per month; *provided, however*, that in no event shall such rate exceed the maximum legal annual interest rate. A Party may also charge for the actual costs of collection, including reasonable attorney fees and any administrative expenses actually incurred. The payment of such interest, costs and/or fees shall not limit a Party from exercising any other rights it may have as a consequence of the lateness of any payment.

**8.8. No Other Compensation.** Neither Party will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other hereunder, except as otherwise expressly set forth herein.

**8.9. Method of Payment.** All payments due from Licensee to Licensor under this Agreement shall be paid in U.S. Dollars by wire transfer or electronic funds transfer of immediately available funds to the account specified by Licensor from time to time upon at least thirty (30) days notice:

**8.10. Currency Conversion.** In the case of Net Sales outside the United States, payments received by Licensee will be expressed in the U.S. Dollar equivalent calculated on a quarterly basis in the currency of the country of sale and converted to their U.S. Dollar equivalent using the average rate of exchange over the applicable calendar quarter to which the sales relate, in accordance with the rate of exchange for such currency reported in The Wall Street Journal, Internet U.S. Edition at [www.wsj.com](http://www.wsj.com), as of the last day of the applicable reporting period (or, if unavailable on such date, the first date thereafter on which such rate is available).

**8.11. Records and Audits.** Licensee will keep complete and accurate records of the underlying revenue data relating to the calculations of Net Sales generated in the then current calendar year and during the

preceding seven (7) calendar years. Licensor will have the right, once annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to Licensee's prior written consent (which shall not be unreasonably withheld), review any such records of Licensee and its Affiliates and Sublicensees (the "**Audited Party**") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of the payments made under Section 8.5 within the twenty four (24) month period preceding the date of the request for review. No calendar year will be subject to audit under this Section 8.11 more than once. The Audited Party will receive a copy of each such report concurrently with receipt by the Licensor. Should such audit certify a discrepancy to the Licensor's detriment, the Audited Party will, within forty-five (45) days after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy. The Licensor will pay the full cost of the review unless the underpayment of amounts due to the Licensor is certified to be greater than five percent (5%) of the amount due for the entire period being examined, in which case the Audited Party will pay the cost charged by such accounting firm for such review. Should the audit lead to the discovery of a discrepancy to the Audited Party's detriment, the Audited Party may credit the amount of the discrepancy, without interest, against future payments payable to the Licensor under this Agreement, and if there are no such payments payable, then the Licensor shall pay to the Audited Party the amount of the discrepancy, without interest, within forty-five (45) days of the Licensor's receipt of the report.

**8.12. Taxes.**

8.12.1. **Withholding.** If any Applicable Law requires Licensee to withhold taxes with respect to any payment to be made by Licensee pursuant to this Agreement, Licensee will notify Licensor of such withholding requirement prior to making the payment to Licensor and provide such assistance to Licensor, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in Licensor's efforts to claim an exemption from or reduction of such taxes. Licensee will, in accordance with such Law, withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish Licensor with proof of payment of such taxes within thirty (30) days following the payment. If taxes are paid to a tax authority, Licensee shall provide reasonable assistance to Licensor to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid.

8.12.2. **VAT.** All payments due to Licensor from Licensee pursuant to this Agreement shall be paid exclusive of any value-added tax ("**VAT**") (which, if applicable, shall be payable by Licensee upon receipt of a valid VAT invoice). If Licensor determines that it is required to report any such tax, Licensee shall promptly provide Licensor with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 8.12.2 is not intended to limit Licensee's right to deduct value-added taxes in determining Net Sales.

**8.13. Payment Disputes.** If Licensee, in good faith, disputes: i) a payment under Milestone Events 1 or 3 in Section 8.2.1; or ii) a payment under Section 8.2.2, then it shall promptly notify Licensor of such dispute and provide Licensor with relevant supporting documentation, in which case the Parties shall promptly meet to discuss and resolve the dispute. If the Parties cannot resolve the dispute informally, they shall refer such dispute for resolution pursuant to Section 14.

**9. INTELLECTUAL PROPERTY AND INVENTIONS.**

**9.1. Ownership of Inventions.** With the understanding that Licensor may assign any and all of its rights to PMI, ownership of inventions, developments or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by the Parties or their Affiliates, or any of its or their employees, independent contractors or agents in the course of Developing, Manufacturing or Commercializing Licensed Products under this Agreement during the Term ("**Inventions**"), and any and all intellectual property rights therein, shall be determined based on the principles of inventorship in accordance with United States patent laws.

Any Invention invented by Licensor and/or PMI shall be owned solely by Licensor or PMI, and shall be licensed to Licensee in accordance with the terms and conditions of this Agreement and shall be Licensed Technology. This Agreement will be understood to be a joint research agreement under 35 U.S.C. 100(h) and 102(c), entered into for the performance of experimental, developmental, or research work in the field of the invention, for the purpose of researching and developing Licensed Products under the terms set forth herein.

**9.2. Licensor Patent Rights.** Licensor shall have the sole right, but not the obligation, to file, prosecute and maintain all Licensor Patent Rights using patent counsel selected by Licensor. Licensee shall not disclose to Third Parties the existence of any unpublished patent applications that are Licensor Patent Rights, or any Know-How contained therein that is not otherwise disclosed publicly at the time of filing of any such unpublished patent applications. Licensee shall reimburse Licensor for all of Licensor's reasonable out of pocket costs incurred in filing, prosecuting and maintaining the Licensor Patent Rights, which amount shall be reduced, on an equal basis, between Licensor and any Third Party(ies) to whom Licensor licenses or grants rights under Licensor Patent Rights for any use or indication other than the Indication. Licensee may opt out of reimbursement of such out of pocket costs with respect to any country within the Territory, in which case the Territory shall be amended to exclude such country and Licensee shall have no right to Commercialize Licensed Products in such country.

**9.3. Process.** Licensor shall reasonably inform and consult with Licensee on the preparation, prosecution and maintenance of Licensor Patents, including providing Licensee with copies of draft documents and filings reasonably in advance of any filing for Licensee's review and comment. Licensor shall consider in good faith any changes reasonably requested by Licensee to such documents promptly upon their being received. Licensor shall promptly provide Licensee with a copy of material communications from any patent authority in the Territory regarding the Licensor Patents, and shall provide drafts of any material filings or material responses to be made to such patent authorities reasonably in advance of submitting such filings or responses so that Licensee may have an opportunity to review and comment thereon. If Licensor disagrees with any of Licensee's comments, it shall consult with Licensee in good faith to reach a mutually agreeable position. If Licensor elects not to prosecute or maintain patent protection on any Licensor Patents, Licensor shall notify Licensee at least ninety (90) days before any such Patent Rights would become abandoned or otherwise forfeited, and Licensee shall have the right (but not the obligation), at its sole cost and expense, to prosecute and maintain such Licensor Patents. Each Party shall provide the other Party with all reasonable assistance and cooperation, at the request and expense of the requesting Party, in patent prosecution and maintenance efforts, including providing all necessary powers of attorney and executing any other required documents or instrument for such prosecution. The Parties will confer regarding the desirability of seeking in any country any patent term adjustment, patent term extension, supplemental patent protection or related extension of rights with respect to Licensor Patents.

**9.4. Data Exclusivity.** Licensee will have the sole right and authority for securing, maintaining and enforcing exclusivity rights that may be available under Applicable Law in a country for a Licensed Product, including regulatory or statutory exclusivity periods. Licensor will cooperate fully with and provide all reasonable assistance to Licensee and use all commercially reasonable efforts consistent with its obligations under Applicable Law (including any applicable consent order or decree) to seek, maintain and enforce all data exclusivity periods available for Licensed Products.

**9.5. Third Party Claims and Enforcement.**

9.5.1. **Notice.** If the Exploitation of Licensed Products in the Territory results in a claim of infringement by a Third Party of any Patent Rights of such Third Party (a "**Product Infringement Claim**"), the Party first having notice thereof shall promptly notify the other Party in writing, setting forth the facts of the claim in reasonable detail. Each Party shall consult with the other Party regarding the strategy for such defense or action in the Territory and keep the other Party reasonably informed regarding the same.



9.5.2. **Enforcement of Patent Rights.** Each Party shall notify the other Party promptly of any Third Party conduct that it reasonably believes is a potential infringement of Licensor Technology in the Territory. The Parties shall thereafter consult and cooperate fully to investigate and determine a course of action. Licensee shall have the first right, but not the obligation, to enforce Licensor Technology against potential Third Party infringement in the Territory for the Indication (and to defend any declaratory judgment action alleging the invalidity, unenforceability or non-infringement of any such Patent Right). Licensor shall have the first right, but not the obligation, to enforce Licensor Technology against potential Third Party infringement in the Territory for any uses or indications other than the Indication. The Party initiating the action under this Section 9.5.2 shall have control over the handling of the litigation, including the selection of counsel and settlement; *provided, however*, that no Party shall settle any action with respect to Licensor Technology without the specific written consent of Licensor and no Party shall settle any action in a matter that will substantially adversely affect the rights of the other Party in the Territory (including the licenses granted herein) without the consent of such other Party, which consent shall not be unreasonably withheld; *provided further* that such other Party shall have the right (except in the case of a conflict) to be represented in such action by separate counsel of its own choice at its own expense. The Party controlling such litigation shall keep the other Party reasonably informed about the status and developments in such action, including considering, in good faith, the input of the other Party regarding the strategy and handling of the litigation. Each Party shall cooperate fully and provide each other with information or assistance that the other Party may reasonably request in connection with any defense, enforcement, litigation or other action initiated pursuant to this Section 9.5.2, including voluntarily consenting to be named as a party in an action commenced or defended by the other Party.

9.5.3. **Expenses and Recoveries.** A Party bringing a claim, suit or action under Section 9.3.2 shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages from such Third Party in such suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amount shall be retained by the enforcing Party.

9.6. **Further Actions.** Each Party shall cooperate with the other Party to execute all documents and take all reasonable actions requested by the other Party to effect the intent of this Article 9.

## 10. REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMERS; LIMITATION OF LIABILITY.

10.1. **Representations and Warranties of the Parties.** Each Party hereby represents and warrants to the other Party that:

10.1.1. such Party (i) is a corporation duly organized and subsisting under the laws of its jurisdiction of organization and (ii) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;

10.1.2. such Party has the power, authority and legal right, and is free to enter into this Agreement and, in so doing, will not violate any other agreement to which such Party is a party, or conflict with the rights granted to any Third Party or Affiliate;

10.1.3. this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity;

10.1.4. such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement;

10.1.5. such Party has obtained all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder;

10.1.6. the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws, limited partnership agreement, or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which such Party is bound;

10.1.7. there is no pending, nor, to the knowledge of a Party any threatened investigation or audit of such Party by the FDA, EMA, or other governmental entity and/or agency which is a counterpart of the FDA or EMA, that could impact either Party's ability to commercialize the Licensed Product;

10.1.8. such Party is not currently suspended or excluded from participating, or otherwise ineligible to participate, in any national health insurance program or system or other governmental reimbursement program in any country of the Territory, or in any governmental procurement or non-procurement programs in the Territory, or otherwise excluded from contracting with the government of any country in the Territory; and

10.1.9. all of the activities it takes under or pursuant to this Agreement shall comply with all Applicable Law, rules and regulations, including, without limitation, the applicable anticorruption laws and regulations relevant to the Development, Manufacture, supply and Commercialization of Licensed Product in the Territory.

**10.2. Additional Licensor Warranties.** As of the Effective Date, Licensor warrants to **Licensee** that:

(a) The Licensor Patent Rights are licensed from Poly-Med Inc. under an exclusive license to Licensor.

(b) Neither Licensor nor PMI nor any of their Affiliates have granted any rights to any Third Party or any Affiliate to such Licensor Patent Rights with respect to any Licensed Product for the Indication;

(c) Licensor has not entered, and shall not enter, into any agreement with any Third Party, PMI or Affiliate that is in conflict with the rights granted to Licensee under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to Licensee under this Agreement;

(d) **Exhibit A** is a complete and accurate list of all Licensor Patent Rights existing as of the Effective Date;

(e) No patent application or registration within Licensor Patent Rights is subject of any pending interference, opposition, cancellation or patent protest;

(f) **Exhibit C** lists all Third Party licenses and agreements pursuant to which Licensor or its Affiliates has obtained license rights to Licensor Patent Rights and Licensor Know-How, and Licensor has shared with Licensee complete and accurate copies of all such licenses and agreements;

(g) No Third Party has made any claim or allegation to Licensor, its Affiliates or PMI in writing that a Third Party has any right or interest in or to Licensor Patent Rights;

(h) To Licensor's knowledge, no Third Party is infringing the Licensor Patent Rights and no Third Party has misappropriated any Licensor Know-How;

(i) There is no claim or litigation that has been brought or threatened by any Third Party alleging that Licensor Patent Rights are invalid or unenforceable; and

(j) Licensor has not intentionally withheld any information in Licensor's and its Affiliates control that is material to Licensee's decision to enter into this Agreement. To Licensor's knowledge, all information disclosed at any time prior to the Effective Date by Licensor and its Affiliates relating to the Licensor Technology is true and accurate and complete. Additionally, to Licensor's knowledge, Licensor has not failed and will not fail to disclose to Licensee any material information known to Licensor and its Affiliates and in its possession and control that would be required to be disclosed in order to make the information relating to the Licensor Technology that have been disclosed not misleading.

**10.3. Licensee Warranties.** Licensee warrants to Licensor that

Licensee has the commercial expertise to market the Licensed Product for the Indication in the Territory and will use Commercially Reasonable Efforts to sell Licensed Product on a FIFO (First-In, First-Out basis).

**10.4. Disclaimers.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY REPRESENTATIONS OR WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING THE LICENSED PRODUCTS, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS OR WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

**11. CONFIDENTIALITY.**

**11.1. Confidential Information.** For the Term and for a period of ten (10) years thereafter, each Party shall maintain in confidence all Know-How and other information of the other Party disclosed or provided to it by the other Party thereof ("**Confidential Information**"). Confidential Information shall include Know-How generated hereunder and Know-How regarding intellectual property and confidential or proprietary Know-How of Third Parties, in each case as disclosed by one Party to the other Party. The terms and conditions of this Agreement also shall be deemed Confidential Information of both Parties.

**11.2. Degree of Care; Permitted Use.** Each Party shall take reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own Confidential Information of a similar nature, and in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably necessary or useful for such purposes. All Confidential Information of a Party, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to those of its directors, officers, employees, actual or potential acquirers or investors, independent

contractors, actual or potential Sublicensees, actual or potential assignees, agents, and external advisors directly involved in or concerned with the carrying out of this Agreement, on a strictly applied “need to know” basis; *provided, however*, that such persons and entities are subject to confidentiality and non-use obligations at least as stringent as the confidentiality and non-use obligations provided for in this Article 11, and each Party shall be responsible for any actions of its employees or Sublicensees as if such actions were taken by the Party itself.

**11.3. Exceptions.** The obligations of confidentiality and non-use set forth in Section 11.1 shall not apply to any portion of Confidential Information that the receiving Party can demonstrate was (i) known to the general public at the time of its disclosure to the receiving Party, or thereafter became generally known to the general public, other than as a result of wrongful actions or omissions of the receiving Party or anyone to whom the receiving Party disclosed such portion; (ii) known by the receiving Party prior to the date of disclosure by the disclosing Party, as shown by the receiving Party’s written records kept in the ordinary course of its business; (iii) disclosed to the receiving Party on an unrestricted basis from a source unrelated to the disclosing Party, as shown by the receiving Party’s written records kept in the ordinary course of its business, where such source is not under a duty of confidentiality to the disclosing Party; or (iv) independently developed by the receiving Party by personnel that did not have access to or use of Confidential Information of the disclosing Party, as shown by the receiving Party’s written records kept in the ordinary course of its business. Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the receiving Party unless the combination itself are published or known to the general public or are in the rightful possession of the receiving Party.

**11.4. Permitted Disclosures.** The obligations of confidentiality and non-use set forth in Section 11.1 shall not apply to the extent that the receiving Party is required to disclose Know-How pursuant to (i) an order of a court of competent jurisdiction, (ii) Applicable Law, (iii) regulations or rules of a securities exchange, (iv) requirement of a governmental agency for purposes of obtaining approval to test or market Licensed Product, (v) subject to the terms of Section 11.1, disclosure of Confidential Information to a patent office for the purposes of filing Patent Rights, or (vi) the exercise by each Party of its rights granted to it under this Agreement or its retained rights; *provided that*, to the extent allowed under Applicable Law, (a) in the case of (i) through (iv), the receiving Party shall provide prior written notice thereof to the disclosing Party and sufficient opportunity for the disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor, and (b) in the case of (vi), such disclosure is made under confidentiality obligations and restrictions on use comparable to those set forth in this Article 11.

**11.5. Return of Confidential Information.** Each Party shall return or destroy, at the other Party’s instruction, all Confidential Information of the other Party in its possession upon expiration or termination of this Agreement, or destroy such Confidential Information, at the disclosing Party’s election and written request. The receiving Party shall provide a written confirmation of such destruction within thirty (30) days of such destruction; *provided, however*, that the foregoing shall not apply to any Confidential Information that is necessary to allow such Party to perform its obligations or exercise any of its rights that expressly survive the termination or expiration of this Agreement.

**11.6. Public Disclosure.** The Parties agree that the initial public announcement of the execution of this Agreement shall be in the form of the press release attached to this Agreement as **Exhibit E**. Thereafter, during the Term, each Party shall submit to the other Party for review and approval all proposed press releases and other publications and public presentations relating to the Licensor Technology, Licensed Products or this Agreement that have not been previously disclosed. Each Party shall provide copies of any such publications and presentations issued by such Party to the other Party within fifteen (15) business days after such release.

**11.7. Attorney-Client Privilege.** Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the Applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending

or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

## 12. INDEMNITIES; LIABILITY; INSURANCE.

**12.1. Indemnification by Licensee.** Licensee shall indemnify, defend, and hold harmless Licensor and its employees, directors, officers and agents, and their respective successors, heirs and permitted assigns and representatives (the “**Licensee Indemnitees**”), from and against any and all Third Party damages, losses, liabilities, costs and expenses (including without limitation reasonable legal expenses, costs of litigation, and reasonable attorney’s fees) and judgments, whether for money or equitable relief, of any kind, incurred or alleged by such Third Party (“**Losses and Claims**”) in a suit, action or proceeding brought against any Licensor Indemnitees to the extent arising out of or relating to: (i) Development, Commercialization, and those manufacturing standards and specifications of Licensed Products that are instructed by Licensee to Licensor in writing (“**Licensee Standards**”), by or on behalf of Licensee or its Sublicensees, including Losses and Claims based upon product liability, except to the extent reasonably attributable to any negligence, recklessness, willful misconduct, or breach of this Agreement by any Licensor Indemnitee; and (ii) the gross negligence, recklessness, or wrongful intentional acts or omissions of Licensee.

**12.2. Indemnification by Licensor.** Licensor shall defend, indemnify, and hold harmless Licensee and its employees, directors, officers and agents, and their respective successors, heirs and assigns and representatives (the “**Licensee Indemnitees**”) from and against all Losses and Claims in a suit, action or proceeding brought against any Licensee Indemnitees to the extent arising out of or relating to: (i) the Development or Manufacture (except for Licensee Standards) of Licensed Products by or on behalf of Licensor, including Losses and Claims based upon product liability, except to the extent reasonably attributable to any negligence, recklessness, willful misconduct, or breach of this Agreement by any Licensee Indemnitee; and (ii) the gross negligence, recklessness, or wrongful intentional acts or omissions of Licensor.

**12.3. Indemnification Procedure.** Each Party, if seeking indemnification under this Article 12 (the “**Indemnitee**”), shall give prompt written notice of the claim to the other Party (the “**Indemnitor**”); *provided, however*, that any failure or delay in providing such notice will not relieve the Indemnitor of its indemnification obligation, except to the extent it is actually prejudiced by such failure or delay. Each Party shall furnish promptly to the other Party, copies of all papers and official documents received in respect of any Losses and Claims. The Indemnitee shall cooperate as requested by the Indemnitor in the defense against any Losses and Claims. The Indemnitor shall have the right to assume and control the defense of the indemnification claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; *provided, however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential conflict of interest between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the indemnification claim as described in this Section 12.3, the Indemnitee may defend the indemnification claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the indemnification claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the indemnification claim in any manner which would have an adverse effect on the Indemnitee’s interests (including any rights under this Agreement or the scope or enforceability of any Patent Rights or Confidential Information or other rights licensed to Licensee by Licensor hereunder), without the prior written consent of the Indemnitee, which consent, in each case (by Indemnitor or Indemnitee), shall not be unreasonably withheld. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor’s expense and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 11. The Indemnitor shall not be liable for any settlement or other disposition of Losses and

Claims by the Indemnitee which is reached without the written consent of the Indemnitor, which consent shall not be unreasonably withheld.

**12.4. Insurance.** Each Party shall procure and maintain insurance, including commercial general liability insurance, having product and completed operations coverage adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Development, Manufacture or Commercialization of Licensed Product is conducted by such Party pursuant to this Agreement and for a five (5) year period thereafter.

**12.5. Exclusion of Damages.** WITHOUT LIMITING THE PARTIES' OBLIGATIONS AND LIABILITIES UNDER THIS ARTICLE 12, AND EXCEPT FOR DAMAGES CAUSED BY A BREACH OF ARTICLE 11, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

**13. TERM AND TERMINATION.**

**13.1. Term; Expiration.** This Agreement shall not be effective, and shall not come into force or effect, prior to the Effective Date. The term of this Agreement shall commence as of the Effective Date (if any) and, unless sooner terminated as specifically provided in this Agreement, shall continue on a country-by-country basis in the Territory until the later of (i) the expiration of the last-to-expire Valid Claim within the Licensor Patent Rights; and (ii) Licensee's last commercial sale of a Licensed Product (the "**Term**").

**13.2. Termination for Breach.** If either Party believes the other is in breach of one or more of its fundamental obligations under this Agreement, it may give notice of such breach to the other Party, which Party shall have three (3) months in which to remedy such breach. If such alleged breach is not remedied such three (3) months period, the non-breaching Party shall be entitled, in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety, or with respect to the Licensed Product or Licensed Products or to a country or countries in the Territory (each, a "**Terminated Country**") to which such breach applies, upon further notice to the other Party.

**13.3. Termination upon Insolvency.** To the extent permitted under Applicable Law, a non-affected Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country, administrative region, district, or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if such other Party proposes a written agreement of composition or extension of its debts, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within one hundred twenty (120) days after the filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment for the benefit of its creditors. In the event of insolvency by Licensor, Licensor will use its best efforts to make any Third-Party licenses required to produce the Licensed Product available to Licensee.

**13.4. Termination by Licensee.** Licensee may terminate this Agreement, in whole or on a country-by-country basis, in each case for its convenience upon sixty (60) days' notice to Licensor. Irrespective of the date of termination, Licensee will be responsible for all payments due as of the termination, and all payments incurred but not yet due under the Budget.

**13.5. Termination by Licensor.** Licensor may terminate this Agreement upon notice to Licensee as follows:

- (a) Failure to make the investments as required in Section 2.7.

- (b) Failure to exercise Commercially Reasonable Efforts to complete all necessary pre-clinical and clinical studies required to support and submit a PMA, where such failure is not cured within sixty (60) days of Licensee's receipt of a notice.
- (c) Licensee's failure to Commercialize a Licensed Product within six (6) months of PMA approval;
- (d) On a Royalty Country-by-Royalty Country basis, Licensee's failure to Commercialize a Licensed Product in such Royalty Country within three (3) years after the First Commercial Sale, unless (i) the Parties determine there is no basis for filing any regulatory submission for Licensed Product in such Royalty Country, or (ii) Licensee terminates its license in such Royalty Country; or (iii) despite using Commercially Reasonable Efforts to seek Regulatory Approval in such Royalty Country, the Regulatory Authority in such Royalty Country has not granted Regulatory Approval;
- (e) Licensee's failure to conduct the clinical trials as set forth in the Development Plan where such failure is not caused by events outside of Licensee's reasonable control, unless otherwise agreed by the JRC, or unless cured within ninety (90) days of notice from Licensor;
- (f) If a site institutional review board or the FDA determines that Ovaprene is a non-significant risk device for the purpose of the first clinical trial in humans and Licensee determines to conduct the first clinical trial in humans as a non-significant risk device, and upon institutional review board clearance to conduct the first clinical trial in humans Licensee does not enroll a patient in a the first non-significant risk medical device study or clinical trial within six (6) months of the Licensed Product production and release, based on Licensed Product release specifications as determined by Licensee, of Licensed Product supplies adequate for the conduct of the study, and where non-enrollment is not caused by events outside of Licensee's reasonable control;
- (g) Licensee's Development and/or Commercialization of a Competing Product.
- (h) Violation of Export Control Laws as set forth in Section 2.6 (subject to any cure periods provided therein).
- (i) Failure to make any material payment required under Section 8 (Financial Terms) after written notice from the Licensor identifying the unpaid amount and requesting cure of the breach and referencing this Section 13.4; provided, however, that Licensee's withholding of disputed amounts in good faith as permitted by and in accordance with Section 8.13 shall not constitute a failure to make material payment as contemplated in this subsection (i). Any such termination shall become effective at the end of ninety (90) days with respect to any material payment breach which has not been cured (including any interest due) by Licensee.

**13.6. Consequences of Termination.** Upon termination of this Agreement in accordance with the provisions of this Article 13, either in its entirety, with respect to one or more Licensed Product(s) (each such Licensed Product subject to termination, a "**Reverted Product**"), then as of the effective date of such termination the following will apply; *provided, however*, that where this Agreement has been terminated with respect to a Reverted Product in a Terminated Country (but not for the entire Territory), then the following will apply only to such Reverted Product in such Terminated Country, as applicable:

- (a) Regulatory. Licensee shall: (A) transfer or assign, or cause to be transferred or assigned, to Licensor or its designee (or to the extent transfer or assignment is not permitted by Applicable Law, take all reasonable actions to make available to Licensor or its designee) the full benefits (including the right of reference, to the extent consistent with Applicable Law) of all Regulatory Applications, Regulatory Approvals, Regulatory Materials, regulatory dossiers, applications for Pricing Approval, and Pricing Approvals, for the Licensed Product, whether held in the name of Licensee, its Affiliate or a Sublicensee or subdistributor; (B) provide to Licensor or its designee originals of all of the foregoing documents, as well as copies of all correspondence with relevant Regulatory Authorities or Pricing Authorities pertaining to Licensed Products; and (C) take such other

reasonable actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section to Licensor or its designee, at Licensor's cost and expense. Notwithstanding the above, if Licensee cannot complete (A) through (C) as set forth above due to Applicable Law or contracts that prohibit the same, Licensee will take all reasonable actions to make the above available to Licensor or Licensor's designee, at Licensor's cost and expense.

(b) Transition. Licensee shall use Commercially Reasonable Efforts to cooperate with Licensor or its designee to effect a smooth and orderly transition of Commercialization activities with respect to the Licensed Product, at Licensor's cost and expense.

(c) Inventory. Licensor shall have the right, but not the obligation, to purchase from Licensee any or all of the usable inventory of any Licensed Product in Licensee's or its Affiliates' possession as of the date of termination, at a purchase price equal to the price paid by Licensee for such inventory. Any packaging, transport, insurance and other costs relating to delivery shall be borne by Licensor. In addition, if Licensor does not purchase the inventory, Licensee and its Affiliates and Sublicensees may sell, have sold and offer to sell any inventory of Licensed Product in its or their possession as of the termination date during the 180-day period beginning on the termination date, or if applicable, complete performance of any and all bid and tender agreements that had been entered into prior to the termination date. Notwithstanding the above, Licensee may not sell off any inventory at a price less than the fair market value.

(d) Promotional Materials. Licensee shall, if requested by Licensor, deliver to Licensor all Promotional Materials in Licensee's or its Affiliates' possession (including electronic files of all Promotional Materials), and Licensor will reimburse Licensee for its out-of-pocket cost for printing and delivering such materials.

(e) Data. Licensee shall transfer to Licensor any and all data exclusivity rights that may be available under Applicable Law in a country for a Licensed Product, including regulatory or statutory exclusivity periods. .

(f) Commercial Agreements. Licensee shall promptly provide to Licensor a list of all agreement in effect between Licensee and any distributors of Licensed Products in the Territory, including the identity of and contact information for each such Third Party, and will use Commercially Reasonable Efforts to facilitate introductions between Licensee and such Third Parties, and Licensee will disclose copies of such agreements to Licensor to the extent permitted by the relevant Third Party (either through the agreement itself, or through the Third Party's written consent). Licensee shall use Commercially Reasonable Efforts to include in each such agreement a provision allowing Licensee to assign such agreement to Licensee in the event of termination of this Agreement.

(g) Sublicensees. The licenses granted by Licensor to Licensee under Section 2 will terminate; provided that any sublicenses granted in accordance with Section 2.2 shall survive if the relevant Sublicensee agrees in writing to be bound by the terms of this Agreement as such terms apply to such Sublicensee (in which event, such Sublicensee will be deemed a direct licensee of Licensor); provided, further, that any such Sublicensee shall only be responsible for any payments that become due as a result solely of such Sublicensee's activities after the effective date of any such termination.

(h) Return of Confidential Information. Upon termination or expiration of this Agreement, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided, however, that: (a) Licensor shall not be obligated to return, delete or destroy any such materials that contain Confidential Information of Licensee that are provided by Licensee to Licensor under this Section 13.6 to the extent necessary or useful for the use, sale, offer for sale, import or Commercialization of Licensed Product in the Territory; and (b) each Party may retain one copy of such materials in its secure archives solely (i) for the purpose of



monitoring compliance with its obligations under this Agreement or (ii) as necessary to comply with Applicable Laws.

**13.7. INTENTIONALLY DELETED.**

**13.8. Surviving Obligations.** The following provisions shall survive the termination or expiration of this Agreement, as applicable: Sections 5.5, 9.1, 13.3, 13.8, 13.9, and Articles 11, 12, 14 and 15. Without limiting the foregoing, termination or expiration of this Agreement shall not relieve either Party from obligations that are expressly indicated to survive termination of this Agreement or relieve either Party of any obligation accruing prior to termination. Any termination of this Agreement or this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement or this Agreement, as applicable, prior to expiration or termination, including the obligation to make any payments under this Agreement. Termination by a Party shall not be an exclusive remedy and all other remedies will be available to the terminating Party, in equity and at law.

**13.9. Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Licensor are, and are intended by the Parties to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 91 of the United States Bankruptcy Code or any applicable foreign equivalent thereof. As a licensee of such rights under this Agreement, Licensee shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code or any applicable foreign equivalent thereof. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Licensor under the United States Bankruptcy Code, Licensee shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the Licensee’s possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the Licensee’s written request therefor, unless Licensor elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of Licensor upon written request therefor by Licensee. Further, each Party agrees and acknowledges that all payments made pursuant to Article 8 of this Agreement constitute “royalties” within the meaning of Section 365(n) of the Bankruptcy Code.

**14. DISPUTE RESOLUTION.**

**14.1. Exclusive Dispute Resolution Mechanism.** If the Parties cannot reach agreement through good faith negotiation to resolve any dispute, controversy or claim arising out of or in connection with this Agreement and any other agreement entered into pursuant hereto or in connection herewith (including matters relating to any Party’s rights or obligations hereunder or regarding the construction, interpretation, and enforceability of such agreements) (collectively, “Disputes”), the procedures set forth in this Article 14 shall be the exclusive mechanism for resolving any such Dispute between the Parties that may arise from time to time except as set forth in Article 3 (or unless otherwise set forth herein).

**14.2. Resolution by Executive Officers.** Except as otherwise provided in this Agreement, in the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute through negotiation and consultation between the Parties. In the event that such Dispute is not resolved on an informal basis within thirty (30) days after one Party provides notice to the other Party of such Dispute, either Party may, by written notice to the other Party, escalate the good faith negotiation of such Dispute. Such escalated Disputes shall be referred to the Executive Officers, who shall have a period of sixty (60) days to resolve the Dispute. If any matter is not resolved under the foregoing provisions, either Party may, at its sole discretion, seek resolution of such Dispute in accordance with Section 14.3.

**14.3. Arbitration.**

14.3.1. If the Parties are unable to resolve the Dispute informally, the Dispute shall be settled by arbitration administered by the AAA before a single arbitrator in accordance with the Commercial AAA rules then pertaining, except where those rules conflict with this provision or any other provision of this Agreement, in which case this provision or Agreement controls. The arbitrator shall be an attorney with no less than ten (10) years' experience in intellectual property law and experience in the law related to the development of medical devices or drugs. The arbitration shall be heard in New York, New York. Within thirty (30) days of initiating arbitration, the parties shall reach agreement upon and thereafter follow procedures assuring to the extent possible that the arbitration will be concluded and the award rendered within no more than six (6) months from selection of the arbitrator. Failing such agreement or an agreement on which AAA rules shall apply to the matter, the arbitrator will design and the Parties will follow such procedures. CONSISTENT WITH THE LIMITATIONS ON LIABILITY STATED IN THIS AGREEMENT, THE PARTIES AGREE NEITHER TO REQUEST NOR SEEK TO ENFORCE ANY PUNITIVE, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES FROM THE ARBITRATOR AND THE ARBITRATOR SHALL NOT BE EMPOWERED TO GRANT ANY SUCH DAMAGES UNDER THIS AGREEMENT, EXCEPT AS PERMITTED IN SECTION 12.4. The arbitrator shall issue a reasoned award. The proceedings shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard both Parties' Confidential Information. The fees of the arbitrator shall be split equally between the Parties, except that a Party shall be responsible for all of the arbitrator's fees if: (1) the arbitrator determines that such Party's positions in the dispute were frivolous or based in bad faith; (2) arbitration is required to resolve a dispute under Section 8.7, and the dispute is resolved against such Party; or (3) an arbitration is required to resolve a dispute as to whether termination of this Agreement was proper under Section 13.5(a), and the dispute is resolved against such Party. The prevailing Party in any such proceeding shall be entitled to reimbursement of its reasonable attorneys' fees and arbitration expenses.

14.3.2. The Parties hereby consent to the jurisdiction of the any court in New York, New York for the enforcement of these provisions and to the jurisdiction of any court having jurisdiction for the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction shall enforce this clause and enter judgment on any award.

14.3.3. Notwithstanding the provisions of this Section, each Party has the right to pursue any provisional relief by court action, such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed. The Parties acknowledge that monetary damages may be an inadequate remedy for any breach by a Party of its nondisclosure obligations under this Agreement, and that the nonbreaching Party shall be entitled to injunctive relief and specific performance to enforce the breaching Party's non-disclosure obligations, in addition to whatever remedies the nonbreaching Party may be entitled to. In the case of either Party seeking relief under this paragraph the Party seeking such relief shall be free to file an action in the state or federal courts in New York, New York with all other matters to be referred to the other dispute resolution procedures of this Agreement.

## 15. MISCELLANEOUS.

15.1. **Assignment.** Neither Party may assign this Agreement without prior written consent from the other Party which shall not be unreasonably withheld, conditioned or delayed, except that no such consent shall be required for either Party to assign its rights or transfer its obligations to its Affiliate or in connection with the sale or transfer of the majority of its stock or all or substantially all of its assets or of the business to which this Agreement relates, whether as part of a merger, sale of stock, sale of assets or other change in control or operation of law. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successor's and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 15.1 shall be null and void. Any agreement that provides for an assignment of this Agreement shall be consistent with and subject to the terms and conditions of this Agreement

and shall oblige the assignee to comply with all the terms of this Agreement. The Party assigning this Agreement shall promptly furnish the other Party with a fully signed photocopy of all assignment agreements.

**15.2. Notices.** Subject to the exception set out below in this Section 15.3, all communications hereunder shall be in writing, electronic mail or by confirmed fax, and shall be deemed to have been duly given (i) upon personal delivery, (ii) upon delivery by a recognized commercial courier or registered mail, provided, that notice which was sent in accordance with this Section 15.3 and the addressee has refused to accept its delivery shall be deemed as duly delivered on the day the annotation on refusal of delivery has been made by the delivering party, or (iii) one (1) business day after confirmation of transmission, if sent by electronic mail or fax, to the e-mail address or fax number set forth below or such other address, e-mail address or fax number as either Party may specify by notice sent in accordance with this Section 15.1:

If to Licensor, addressed to:

ADVA-Tec, Inc.  
51 Technology Drive, Suite B  
Anderson, SC 29625  
Telephone: 864-506-0097

If to Licensee, addressed to:

DARÉ Bioscience, Inc.  
Attn: Chief Executive Officer

Notwithstanding any provision to the contrary, the delivery of any notice relating to the exercise of the rights of the Parties to terminate the Agreement as provided for in Article 14, including notices alleging the occurrence of an event which may give rise to Party's right to terminate the Agreement, shall be delivered by recognized commercial courier or registered mail.

**15.3. Further Actions.** At the request of the other Party, each Party shall execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.4. Force Majeure.** Neither Party shall be liable or responsible to the other Party for loss or damages, nor shall it have any right to terminate this Agreement for any default or delay attributable to any event beyond its reasonable control and without its fault or negligence, including acts of God, acts of government (including injunctions and clinical holds), fire, flood, earthquake, strike, lockout, labor dispute, breakdown of plant, shortage of critical equipment, loss or unavailability of manufacturing facilities or material, casualty or accident, civil commotion, acts of public enemies, acts of terrorism or threat of terrorist acts, blockage or embargo and the like; *provided, however*, that in each such case the Party affected shall use commercially reasonable efforts to avoid such occurrence and to remedy it promptly. The Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled, and the Party receiving notice shall be similarly excused from its respective obligations which it is thereby disabled from performing; *provided, however*, that such affected Party commences and continues to take reasonable and diligent actions to cure such cause.

**15.5. Amendment.** No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

**15.6. Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

**15.7. Construction.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of

any gender shall be applicable to all genders. The words “including”, “includes” and “such as” are used in their non-limiting sense and have the same meaning as “including without limitation” and “including but not limited to”. The term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.” The word “will” shall be construed to have the same meaning and effect as the word “shall.” The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

**15.8. Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of New York without regard to its or any other jurisdiction’s choice of law rules that would result in the application of the laws of any jurisdiction other than New York. All questions concerning the construction or effect of Patent Rights shall be decided in accordance with the laws of the country in which the particular Patent Right concerned has been filed or granted, as the case may be.

**15.9. Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

**15.10. Entire Agreement.** This Agreement and the Exhibits attached hereto, together with agreements the conclusion of which is contemplated herein upon their conclusion, constitute and contain the complete, final and exclusive understanding and agreement of the Parties, and cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof (and for the avoidance of doubt including the Non-Binding Term Sheet for License Agreement dated August 12, 2015, as amended by the Parties on November 11, 2015, which are hereby superseded and terminated). Neither Party shall be liable to nor bound by the other Party in any manner by any representations, warranties, covenants or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon any party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided herein.

**15.11. Counterparts; Electronic Delivery.** This Agreement may be executed simultaneously in two or more counterparts, any of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in “portable document format” (“.pdf”), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

[Signature Page Follows]

**CONFIDENTIAL TREATMENT REQUESTED**

In Witness Whereof, the Parties have executed this Agreement as of the Signature Date, and this Agreement shall be effective, if at all, as of the Effective Date.

**DARÉ BIOSCIENCE, INC.**      **ADVA-TEC, INC.**

By: /s/ Sabrina Martucci Johnson By: /s/ [\*\*\*]

Name: Sabrina Martucci Johnson Name: [\*\*\*]

Title: Chief Executive Officer      Title: President

Date: March 19, 2017                      Date: March 19, 2017

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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## EXHIBIT A

## Licensor Patent Rights

PMI REF	APP #	PATENT/REG #	TITLE	DATE FILED	STATUS
SHA-52-CIP	10/935,808	8,399,013	PARTIALLY ABSORBABLE FIBER-REINFORCED COMPOSITES FOR CONTROLLED DRUG DELIVERY	9/8/2004	Issued
SHA-52	10/860,677	8,404,272	COMPOSITE ABSORBABLE/BIODEGRADABLE RINGS FOR CONTROLLED DRUG DELIVERY	6/3/2004	Issued
SHA-52-CON	13/766,907	9,084,717	PARTIALLY ABSORBABLE FIBER-REINFORCED COMPOSITES FOR CONTROLLED DRUG DELIVERY	02/14/2013	Issued
SHA-52-CON_II	13/771,201	8,992,968	COMPOSITE ABSORBABLE/BIODEGRADABLE RINGS FOR CONTROLLED DRUG DELIVERY	02/20/2013	Issued
SHA-52-CON-B	14/669,105	9,370,574	COMPOSITE ABSORBABLE/BIODEGRADABLE RINGS FOR CONTROLLED DRUG DELIVERY	03/26/2015	Issued
SHA-52-CIP-CON-B	14/707,453	9,308,168	COMPOSITE ABSORBABLE/BIODEGRADABLE RINGS FOR CONTROLLED DRUG DELIVERY	05/08/2015	Issued
SHA-52-CIP-EP	EP 04811105.8	EP1786356 B1	PARTIALLY ABSORBABLE FIBER-REINFORCED COMPOSITES FOR CONTROLLED DRUG DELIVERY	1/31/2007	Granted
SHA-52-EP	EP 04755812.7	EP1648338 B1	COMPOSITE ABSORBABLE/BIODEGRADABLE RINGS FOR CONTROLLED DRUG DELIVERY	6/22/2004	Granted
SHA-60-US	11/667,933	8,057,817	INTRAVAGINAL RINGED MESH DEVICE AND APPLICATOR THEREFOR	12/14/2005	Issued
SHA-60-CIP-DIV	13/272,351	8,506,988	MULTICOMPONENT BIOACTIVE INTRAVAGINAL RING	10/13/2011	Issued
SHA-60-CIP	11/974,140	8,062,658	MULTICOMPONENT BIOACTIVE INTRAVAGINAL RING	10/11/2007	Issued
SHA-60-EP	EP 05853990.9	EP1827328 B1	INTRAVAGINAL RINGED MESH DEVICE	6/6/2007	Granted

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**CONFIDENTIAL TREATMENT REQUESTED**

<b>SHA-60-CIP-EP</b>	EP 08836926.9		MULTICOMPONENT BIOACTIVE INTRAVAGINAL RING	10/9/2008	Pending
<b>SHA-60-CIP-EP-HK</b>	HK12108153.2		MULTICOMPONENT BIOACTIVE INTRAVAGINAL RING	08/20/2012	Pending
<b>SHA-121-PCT-US</b>	15/301,281		CONTRACEPTIVE AND RELATED DEVICE	04/01/2015	Pending
<b>SHA-121-CA</b>	2944436		CONTRACEPTIVE AND RELATED DEVICE	04/01/2015	Pending
<b>SHA-121-CN</b>	201580025821.3		CONTRACEPTIVE AND RELATED DEVICE	04/01/2015	Pending
<b>SHA-121-EP</b>	15774399.8		CONTRACEPTIVE AND RELATED DEVICE	04/01/2015	Pending
<b>SHA-121-IN</b>	201617036424		CONTRACEPTIVE AND RELATED DEVICE	04/01/2015	Pending
<b>SHA-121-JP</b>	2016-560390		CONTRACEPTIVE AND RELATED DEVICE	04/01/2015	Pending
<b>Ovaprene®</b>	78439767	3160046	INTRAVAGINAL RING FOR CONTRACEPTION	2006	Live

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**EXHIBIT B**

Royalty Countries

[\*\*\*]

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**EXHIBIT C**

Licenses

[\*\*\*]

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**EXHIBIT D**

Development Plan

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**EXHIBIT E**

Press Release

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**EXHIBIT F**

Developing World Countries for which Royalties under section 8.4 are never payable

Developing World Countries means [\*\*\*] and [\*\*\*] specifically:  
[\*\*\*]

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



May 31, 2017

Sabrina Martucci Johnson

Dear Sabrina:

Dare Bioscience, Inc. (the "Company") is pleased to confirm your employment on the following terms:

1. **Position.** Your title is Chief Executive Officer, and you shall report to the Company's Board of Directors. This is a full-time position. While you render services to the Company, you will not engage in any other employment, consulting or other business activity (whether full time or part time) that would create a conflict of interest with the Company or any Company affiliate. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties to the Company. Notwithstanding the above, the Company acknowledges that as of the date of this letter, you are Chief Financial Officer of the California Institute for Biomedical Research and may have responsibilities and obligations related thereto (the "Calibr Obligations"); provided, however, by signing this letter agreement, you confirm to the Company that the Calibr Obligations do not prohibit you from performing your duties to the Company and shall not create a conflict of interest. In the event that a conflict of interest were to arise with respect to the Calibr Obligations, you further agree to notify the Company of such conflict as soon as practicable, but in no event later than two business days from your discovery of such a conflict.

2. **Cash Compensation.** The Company will pay you a salary at the rate of \$41,600 per year, payable in accordance with the Company's standard payroll schedule. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time.

3. **Benefits.** You will be eligible to participate in all benefit programs, if any, that the Company may decide to establish in the future.

4. **Proprietary Information and Inventions Agreement.** Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard Employee Proprietary Information and Inventions Agreement, a copy of which is attached hereto as Exhibit A.

5. **Non-Solicitation; Exclusivity.** During your employment with the Company and for a one year period thereafter, you will not, either directly or indirectly, solicit, induce, recruit or encourage any of the Company's employees or consultants to terminate their relationship with the Company (for purposes of this paragraph, the "Company" shall include the Company and any of its affiliates, including its parent and related corporations). During your employment with the Company, you will not, either directly or indirectly, engage in any employment, business, or activity that is in any way competitive with the business or proposed business of the Company, and will not directly or indirectly assist any other person or organization in competing with the Company or in preparing to engage in competition with the business or proposed business of the Company.

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6. **Employment Relationship.** Employment with the Company is for no specific period of time. Your employment with the Company will be “at will,” meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause. Any contrary representations that may have been made to you are superseded by this letter agreement. This is the full and complete agreement between you and the Company on this term. Although your job duties, title, compensation and benefits, as well as the Company’s personnel policies and procedures, may change from time to time, the “at will” nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

7. **Tax Matters.**

(a) **Withholding.** All forms of compensation referred to in this letter agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law.

(b) **Tax Advice.** You are encouraged to obtain your own tax advice regarding your compensation from the Company. You agree that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or its Board of Directors related to tax liabilities arising from your compensation.

8. **Interpretation, Amendment and Enforcement.** This letter agreement and Exhibit A supersede and replace any prior agreements, representations or understandings (whether written, oral, implied or otherwise) between you and the Company and constitute the complete agreement between you and the Company regarding the subject matter set forth herein. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company (the “Disputes”) will be governed by California law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in California in connection with any Dispute or any claim related to any Dispute.

\* \* \* \* \*

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Proprietary Information and Inventions Agreement and returning them to me. This offer, if not accepted, will expire at the close of business on May 31, 2017. As required by law, your employment with the Company is contingent upon your providing legal proof of your identity and authorization to work in the United States. Your employment is also contingent upon your starting work with the Company on or before May 31, 2017.

If you have any questions, please call me at (858) 769-9145.

Very truly yours,

Daré Bioscience, Inc.

By:  
Hawley

/s/ \_\_\_\_\_ Roger

Roger Hawley, Chairman of the Board

I have read and accepted this employment offer:

/s/ Sabrina Martucci Johnson  
Sabrina Martucci Johnson

1. Attachments

Exhibit A: Employee Proprietary Information and Inventions Agreement

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**EXHIBIT A**

Employee Proprietary Information and Inventions Agreement





May 31, 2017

Lisa Walters-Hoffert

Dear Lisa:

Daré Bioscience, Inc. (the "Company") is pleased to confirm your employment on the following terms:

1. **Position.** Your title is Chief Financial Officer, and you shall report to the Company's Chief Executive Officer. This is a full-time position. While you render services to the Company, you will not engage in any other employment, consulting or other business activity (whether full time or part time) that would create a conflict of interest with the Company or any Company affiliate. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties to the Company.

2. **Cash Compensation.** The Company will pay you a salary at the rate of \$41,600 per year, payable in accordance with the Company's standard payroll schedule. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time.

3. **Benefits.** You will be eligible to participate in all benefit programs, if any, that the Company may decide to establish in the future.

4. **Proprietary Information and Inventions Agreement.** Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard Employee Proprietary Information and Inventions Agreement, a copy of which is attached hereto as Exhibit A.

5. **Non-Solicitation; Exclusivity.** During your employment with the Company and for a one year period thereafter, you will not, either directly or indirectly, solicit, induce, recruit or encourage any of the Company's employees or consultants to terminate their relationship with the Company (for purposes of this paragraph, the "Company" shall include the Company and any of its affiliates, including its parent and related corporations). During your employment with the Company, you will not, either directly or indirectly, engage in any employment, business, or activity that is in any way competitive with the business or proposed business of the Company, and will not directly or indirectly assist any other person or organization in competing with the Company or in preparing to engage in competition with the business or proposed business of the Company.

6. **Employment Relationship.** Employment with the Company is for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause. Any contrary representations that may have been made to you are superseded by this letter agreement. This is the full and complete agreement between you and the Company on this term. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

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7. **Tax Matters.**

(a) **Withholding.** All forms of compensation referred to in this letter agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law.

(b) **Tax Advice.** You are encouraged to obtain your own tax advice regarding your compensation from the Company. You agree that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or its Board of Directors related to tax liabilities arising from your compensation.

8. **Interpretation, Amendment and Enforcement.** This letter agreement and Exhibit A supersede and replace any prior agreements, representations or understandings (whether written, oral, implied or otherwise) between you and the Company and constitute the complete agreement between you and the Company regarding the subject matter set forth herein. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by California law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in California in connection with any Dispute or any claim related to any Dispute.

\* \* \* \* \*

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Proprietary Information and Inventions Agreement and returning them to me. This offer, if not accepted, will expire at the close of business on May 31, 2017. As required by law, your employment with the Company is contingent upon your providing legal proof of your identity and authorization to work in the United States. Your employment is also contingent upon your starting work with the Company on or before May 31, 2017.

If you have any questions, please call me at (858) 769-9145.

Very truly yours,

Daré Bioscience, Inc.

By:  
Johnson

/s/ Sabrina Martucci

Sabrina Martucci Johnson  
Chief Executive Officer

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I have read and accepted this employment offer:

/s/ Lisa Walters-Hoffert  
Lisa Walters-Hoffert

1. Attachments

Exhibit A: Employee Proprietary Information and Inventions Agreement

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**EXHIBIT A**

Employee Proprietary Information and Inventions Agreement



May 31, 2017

Mark Walters

Dear Mark:

Daré Bioscience, Inc. (the "Company") is pleased to confirm your employment on the following terms:

1. **Position.** Your title is Vice President of Operations, and you shall report to the Company's Chief Executive Officer. This is a full-time position. While you render services to the Company, you will not engage in any other employment, consulting or other business activity (whether full time or part time) that would create a conflict of interest with the Company or any Company affiliate. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties to the Company.

2. **Cash Compensation.** The Company will pay you a salary at the rate of \$41,600 per year, payable in accordance with the Company's standard payroll schedule. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time.

3. **Benefits.** You will be eligible to participate in all benefit programs, if any, that the Company may decide to establish in the future.

4. **Proprietary Information and Inventions Agreement.** Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard Employee Proprietary Information and Inventions Agreement, a copy of which is attached hereto as Exhibit A.

5. **Non-Solicitation; Exclusivity.** During your employment with the Company and for a one year period thereafter, you will not, either directly or indirectly, solicit, induce, recruit or encourage any of the Company's employees or consultants to terminate their relationship with the Company (for purposes of this paragraph, the "Company" shall include the Company and any of its affiliates, including its parent and related corporations). During your employment with the Company, you will not, either directly or indirectly, engage in any employment, business, or activity that is in any way competitive with the business or proposed business of the Company, and will not directly or indirectly assist any other person or organization in competing with the Company or in preparing to engage in competition with the business or proposed business of the Company.

6. **Employment Relationship.** Employment with the Company is for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause. Any contrary representations that may have been made to you are superseded by this letter agreement. This is the full and complete agreement between you and the Company on this term. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

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7. **Tax Matters.**

(a) **Withholding.** All forms of compensation referred to in this letter agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law.

(b) **Tax Advice.** You are encouraged to obtain your own tax advice regarding your compensation from the Company. You agree that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or its Board of Directors related to tax liabilities arising from your compensation.

8. **Interpretation, Amendment and Enforcement.** This letter agreement and Exhibit A supersede and replace any prior agreements, representations or understandings (whether written, oral, implied or otherwise) between you and the Company and constitute the complete agreement between you and the Company regarding the subject matter set forth herein. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by California law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in California in connection with any Dispute or any claim related to any Dispute.

\* \* \* \* \*

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Proprietary Information and Inventions Agreement and returning them to me. This offer, if not accepted, will expire at the close of business on May 31, 2017. As required by law, your employment with the Company is contingent upon your providing legal proof of your identity and authorization to work in the United States. Your employment is also contingent upon your starting work with the Company on or before May 31, 2017.

If you have any questions, please call me at (858) 769-9145.

Very truly yours,

Daré Bioscience, Inc.

By:  
Johnson

/s/ Sabrina Martucci

Sabrina Martucci Johnson  
Chief Executive Officer

I have read and accepted this employment offer:

/s/ Mark Walters  
Mark Walters

1. Attachments

Exhibit A: Employee Proprietary Information and Inventions Agreement

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**EXHIBIT A**

Employee Proprietary Information and Inventions Agreement



## CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

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

Date: November 13, 2017

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

## CERTIFICATIONS

I, Lisa Walters-Hoffert, certify that:

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

Date: November 13, 2017

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

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

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

Date: November 13, 2017

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

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

In connection with the Quarterly Report on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

Date: November 13, 2017

/s/ Lisa Walters-Hoffert

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