UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018
OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO_____**

Commission File No. 001-36395

daré bioscience

DARÉ BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-4139823**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)
3655 Nobel Drive, Suite 260 **San Diego, CA** (Address of Principal Executive Offices)	**92122** (Zip Code)

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

Securities registered under Section 12(b) of the Act:

Title of each class:	**Name of each exchange on which registered:**
Common Stock, Par Value $0.0001 Per Share	Nasdaq Capital Market

Securities registered under Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No x

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 x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2018 was approximately $10,682,000 based on the closing price as reported on the Nasdaq Capital Market. This excludes shares of common stock held by affiliates at June 30, 2018. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power directly, or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant. The determination of affiliate status for this purpose may not be conclusive for other purposes.

As of March 29, 2019, there were 11,422,161 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2019 annual meeting of stockholders are incorporated by reference into Part III of this report where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Daré Bioscience, Inc. and Subsidiaries
Form 10-K – ANNUAL REPORT
For the Fiscal Year Ended December 31, 2018
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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, 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 report, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," project," "target," "tend to," or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors described in Part I, Item IA, "Risk Factors," in this report, and elsewhere in this report. Given these uncertainties, you should not place undue reliance on any forward-looking statement. The following factors are among those that may cause such differences:

- *Inability to continue as a going concern;*
- *Inability to raise additional capital, under favorable terms or at all;*
- *Inability to successfully attract partners and enter into collaborations on acceptable terms;*
- *Failure to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates due to limited financial resources;*
- *Inability to develop and commercialize our product candidates;*
- *Failure or delay in starting, conducting and completing clinical trials or obtaining United States Food and Drug Administration, or FDA, or foreign regulatory approval for our product candidates in a timely manner;*
- *A change in the FDA's primary oversight responsibility;*
- *A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FDA's 505(b)(2) pathway;*
- *Unsuccessful clinical trial outcomes stemming from clinical trial designs, failure to enroll a sufficient number of patients, higher than anticipated patient dropout rates, failure to meet established clinical endpoints, undesirable side effects and other safety concerns;*
- *Negative publicity concerning the safety and efficacy of our product candidates, or of product candidates being developed by others that share characteristics similar to our candidates;*
- *Inability to demonstrate sufficient efficacy of our product candidates;*
- *Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;*
- *Monetary obligations and other requirements in connection with our exclusive, in-license agreements covering the patents and related intellectual property related to our product candidates;*
- *Developments by our competitors that make our product candidates less competitive or obsolete;*
- *Dependence on third parties to conduct clinical trials and to manufacture product candidates;*
- *Dependence on third parties to supply clinical supplies and raw materials, drugs and other materials required to produce a finished product and to produce the quantities needed;*
- *Failure of our product candidates, if approved, to gain market acceptance or obtain adequate coverage for third party reimbursement;*

- *A reduction in demand for contraceptives caused by an elimination of current requirements that health insurance plans cover and reimburse FDA-cleared or approved contraceptive products without cost sharing;*
- *Lack of precedent to help assess whether health insurance plans will cover our product candidates;*
- *The reimbursement environment relating to our product candidates at the time we obtain regulatory approval, if ever;*
- *Difficulty in introducing branded products in a market made up of generic products;*
- *Inability to adequately protect or enforce our, or our licensor's, intellectual property rights;*
- *Lack of patent protection for the active ingredients in certain of our product candidates which could expose those product candidates to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in pre-clinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could subject us to securities class-action litigation;*
- *Litigation or public concern about the safety of our potential products;*
- *Strict government regulations on our business, including various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act;*
- *Regulations governing the production or marketing of our product candidates;*
- *Loss of, or inability to attract, key personnel; and*
- *Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.*

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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

ITEM 1. BUSINESS

The terms “we,” “us,” “our,” “Daré” or the “Company” refer collectively to Daré Bioscience, Inc. and its wholly-owned subsidiaries, unless otherwise stated or the context otherwise requires. All information in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

Overview

We are a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women’s health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility.

Our Strategy

Our business strategy is to license or otherwise acquire the rights to differentiated product candidates in women's health, some of which have existing clinical proof-of-concept data, and to advance those candidates through clinical development and regulatory approval on our own or in collaboration with strategic partners.

We believe that there is an opportunity to fill the gap that exists in the development of innovations in women’s health between (a) non-profit organizations, small private companies and individual entrepreneurs that discover, innovate and conduct early-stage research and clinical development of product candidates, and (b) pharmaceutical companies that conduct late-stage clinical development and commercialize approved products. We believe that the development activities between these two ends of this spectrum (early pre-clinical and clinical development of product candidates on the one hand and late-stage clinical trials and commercialization of product candidates on the other) are currently underserved. In addition, we believe there are gaps in treatment options in the women's health market and there is an opportunity to provide therapies that address persistent unmet needs. We intend to fill the mid-stage development gap and to address the gaps in treatment options for women.

The dynamics of the women’s health market provide an opportunity for us to assemble a portfolio of candidates, including clinical-stage candidates, often with published human data. We have licensed or otherwise acquired four clinical-stage product candidates as well as a number of pre-clinical product candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through late stages of development or approval. If successful, we intend to create a comprehensive global commercialization strategy with established pharmaceutical partners and regional distributors. Our global commercialization and development strategy includes partnering with pharmaceutical companies and regional distributors once we have advanced a candidate through mid-stage to late-stage development, including but not limited to entering into co-development and promotion agreements.

Our Clinical-Stage Product Candidates and Programs

We are initially focused on the areas of contraception, vaginal health, sexual health and fertility. We have focused primarily on adding product candidates to our portfolio with pre-clinical and early clinical testing data developed by third parties. Our development strategy is two-fold:

(1) We intend to use existing data and any data we generate to prepare Investigational New Drug Applications, or INDs, or Investigational Device Exemptions, or IDEs, to the extent these have not already been prepared, and to design and implement additional pre-clinical and clinical trials to advance our programs toward the submission of New Drug Applications, or NDAs, or Premarket Approvals, or PMAs, for regulatory approval of our product candidates.

(2) We intend to identify FDA-approved drugs and therapies that might benefit from a different formulation, manner of application or delivery method to enhance therapeutic outcomes and to expedite the development of these candidates under the FDA's 505(b)(2) pathway. We intend to utilize the FDA's 505(b)(2) pathway for three of our four existing clinical-stage candidates.

We believe our product candidates offer innovative therapeutic approaches that may provide meaningful benefits over current treatment options. We are currently developing four clinical-stage product candidates:

- DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis;

- Ovaprene®, a non-hormonal monthly contraceptive intravaginal ring;
- Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder; and
- DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause.

DARE-BV1

In December 2018, we announced that we entered into agreements with Hammock Pharmaceuticals, Inc., TriLogic Pharma, LLC and MilanaPharm LLC, through which we acquired the exclusive global development and commercialization rights to a proprietary hydrogel drug delivery technology formulated with clindamycin, or DARE-BV1 (formerly known as MP-101), for the treatment of bacterial vaginosis, or BV, as well as similar rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological applications in humans. The proprietary *in-situ* gel system we licensed is designed to undergo transition from a viscous liquid to a bioadhesive gel, or solution-to-gel (sol-to-gel) transition, at the site of application using body temperature as the trigger, and release the incorporated active drug over multiple days, enabling single treatment products. In DARE-BV1, this proprietary technology is formulated with clindamycin, an antibiotic used to treat certain bacterial infections including BV, and is designed to produce a dual release pattern after vaginal application (an initial burst with approximately 50% of the active ingredient released in three days, followed by a slow release of the second 50% over the following four days), providing prolonged duration of exposure to clindamycin at the site of infection.

BV is a type of vaginal inflammation caused by the overgrowth of certain bacteria naturally found in the vagina. Symptoms include vaginal discharge, vaginal odor, vaginal pain, itching or burning, and burning during urination. We believe current BV therapies are inadequate and there is a significant unmet need for better treatment. Existing FDA-approved therapies have clinical cure rates (based on Amsel's Diagnostic Criteria) of less than 70%. In an investigator initiated pilot study that enrolled 30 women between the age of 18 to 50, DARE-BV1 demonstrated an 88% clinical cure rate in the evaluable subjects (n=26) at the test-of-cure visit (Day 7-14) after one vaginal administration.

Because BV is a vaginal ailment, many women and providers prefer a treatment administered directly to the infection site over treatments taken orally. This is particularly true for antibiotics given the potential unwanted side effects accompanying oral systemic administration. Given the unique environment of the vagina, we believe one of the major challenges is keeping a vaginally-administered drug or therapeutic agent in place long enough to treat the infection. Our novel hydrogel formulation is designed for extended release (up to seven days) of the active ingredient, clindamycin phosphate 2%, at the site of infection. We believe our hydrogel's unique adhesion properties and release profile led to the encouraging cure rates in the initial pilot study.

We intend to file a new IND during the second half of 2019 and to commence a Phase 3 clinical study of DARE-BV1 in approximately 250 women in the fourth quarter of 2019. If the study is successful, we plan to be in a position to file an NDA with the FDA in 2020. Based on discussions between the prior sponsor, MilanaPharm, and the FDA, we believe that one successful Phase 3 study, with sufficient power and size, would be sufficient for FDA approval of DARE-BV1 to treat BV. We plan to leverage the existing data and established safety profile of other products using clindamycin phosphate to utilize the FDA's 505(b)(2) pathway for approval of DARE-BV1 for treatment of BV in the U.S. We anticipate that the cost for the Phase 3 clinical study, including manufacturing activities, and the NDA filing thereafter to be less than $10.0 million.

Ovaprene

We believe the need for more effective and convenient options is particularly true with contraception. While a variety of hormonal and non-hormonal options exist, there is a notable void: an effective, short-acting, non-hormonal method of contraception that does not require intervention at the time of intercourse.

Ovaprene is designed to provide monthly, hormone-free, convenient (inserted by the woman and worn for multiple weeks) contraceptive protection with "typical use" effectiveness comparable to the most effective barrier option (the diaphragm) and short-acting hormonal options (pill, patches and vaginal ring). Ovaprene is a silicone-reinforced ring with a soft, absorbable scaffolding that encircles a fluid-permeable barrier. A non-braided, multi-filament mesh in the center of the ring functions as a physical barrier to sperm. The silicone ring also releases two ingredients-ascorbic acid and ferrous gluconate-that act together to create a spermiostatic environment within the vagina. If approved, Ovaprene would represent a new category of birth control.

In a postcoital test, or PCT, pilot study conducted in 20 women and published in *The Journal of Reproductive Medicine*® in 2009, Ovaprene demonstrated the ability to immobilize sperm and prevent their progression into the cervical mucus. The study also demonstrated the acceptability of the device to both partners. No colposcopic abnormalities, no significant changes in vaginal flora and no serious adverse effects were observed.

Ovaprene is a combination product that underwent a request for designation process within the Office of Combination Products at the FDA. The FDA designated Center for Devices and Radiological Health, or CDRH, as the lead agency FDA program center for premarket review and product regulation. It also provided notice that CDRH determined that a PMA will be required to market Ovaprene in the U.S.

Our clinical development plan for Ovaprene is guided by the size, structure and results of other barrier contraceptive devices using active agents that obtained FDA approval with CDRH as lead review division because we believe they provide a good indication of the FDA requirements for Ovaprene. Specifically, in addition to demonstrating biocompatibility and safety, we expect the clinical requirements for FDA approval for Ovaprene will include obtaining safety and preliminary efficacy data in a PCT clinical trial, and conducting one large, single-arm safety and efficacy study, the pivotal clinical trial. We have not yet had communications with the FDA regarding the specific PMA requirements for Ovaprene and hence, the requirements for approval may be more extensive and costlier than we currently anticipate.

In May 2018, we announced the initiation of a PCT clinical trial of Ovaprene, which is being conducted in collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Human Development (clinicaltrials.gov identifier: NCT03598088). The study is designed to assess general safety, acceptability, and effectiveness in preventing progressively motile sperm from reaching the cervical canal following intercourse and will enroll approximately 50 couples with a target of having at least 25 women complete a total of 21 visits. Each woman's cervical mucus will be measured at several points during the study. Women will be evaluated over the course of five menstrual cycles, including a baseline measurement excluding the use of any product (during menstrual cycle 1), using a diaphragm (during menstrual cycle 2) and using Ovaprene (during menstrual cycles 3, 4 and 5).

If our ongoing PCT clinical trial demonstrates that Ovaprene is effective in preventing most sperm from progressing into the cervical canal and is safe to use over multiple weeks, we intend to prepare and file an IDE with the FDA to commence a pivotal clinical trial of similar size and duration as the Caya® diaphragm pivotal study, which evaluated pregnancy rates in approximately 250 women over a period of six months. Prior to completing our U.S. pivotal study of Ovaprene, we may seek a Conformite Europeenne, or CE, Mark approval for Europe using a subset of the total pivotal clinical trial population. We believe that the receipt of E.U. or U.S. regulatory approvals can be used to support registration in many other countries around the world.

Sildenafil Cream, 3.6%

Today, there are no FDA-approved products that specifically address the symptoms or underlying pathology of female sexual arousal disorder, or FSAD. Although numerous pharmaceutical products have been developed and approved to treat erectile dysfunction in men, women continue to lack effective options for FSAD, an analogous condition. In February 2018, we announced that we acquired an exclusive worldwide license to develop and commercialize Sildenafil Cream, 3.6%, as a potential treatment for FSAD.

FSAD is characterized primarily by a persistent or recurrent inability to attain or maintain sufficient physical sexual arousal, frequently resulting in distress or interpersonal difficulty. Orally administered sildenafil received FDA approval in 1998 for the treatment of erectile dysfunction in men and is marketed under the brand name Viagra®. Oral sildenafil also demonstrated biological activity when studied in women, but due to differences between male and female physiology, it is expected that a topically administered formulation of sildenafil (applied directly to the genital region) may have advantages over the oral formulation. Sildenafil Cream, 3.6% is a unique, proprietary topical formulation of sildenafil specially formulated for women and designed to be applied directly to the genital tissue. Based on known biological pathways for the molecule, Sildenafil Cream, 3.6% is expected to increase local blood flow to the genital tissue, which we believe will lead to an improvement in genital response and overall sexual experience.

In a Phase 1 clinical study of three escalating doses of topical sildenafil cream (1 g cream with 35 mg sildenafil; 2 g cream with 71 mg sildenafil; and 4 g cream with 142 mg sildenafil) in 20 healthy post-menopausal women using a crossover study design, topical sildenafil demonstrated significantly lower systemic exposure compared to a 50 mg oral sildenafil dose, and topical sildenafil was safe and well tolerated at clinically relevant doses (1-2 g cream). Study subjects reported favorable product characteristics: easy to use and readily absorbed.

In a Phase 2a, single center, single-dose, double-blind, placebo-controlled, 2-way crossover study in 31 women with FSAD (15 pre-menopausal and 16 post-menopausal), topical sildenafil cream demonstrated increases in

measurable blood flow to the genital tissue compared to placebo (mean change in vaginal pulse amplitude, or VPA, analysis) using a vaginal photoplethysmograph approximately 30 minutes post-dosing. VPA uses light technology to indicate changes in vaginal engorgement, wherein higher amplitudes indicate higher levels of blood flow.

In the third quarter of 2018, we had a Type C meeting with the FDA regarding the proposed design of our Phase 2b clinical trial for Sildenafil Cream, 3.6% and the overall development program for this product candidate. Based on the guidance we received from that meeting with the FDA, we commenced Phase 2b related activities during the fourth quarter of 2018 with the initiation of a non-interventional study intended to support the validity of specific patient reported outcome, or PRO, measures to assess efficacy of Sildenafil Cream, 3.6%. This non-interventional study is designed to explore the experience of FSAD and to evaluate the relevance of the selected PRO measures based on patients' own experiences and determine patients' understanding of the items, instructions, and response options of the selected PRO measures. With this study we seek to identify and document the genital arousal symptoms that will be assessed in our planned at-home Phase 2b trial and in our pivotal studies, and to demonstrate that these symptoms are the most important and relevant to our target population and should be acceptable endpoints for the FDA. In parallel, we will continue to explore additional clinical and non-clinical work that might be valuable or required to support the overall program and the anticipated design of the Phase 2b trial. Because our plan is for the co-primary endpoints used in the Phase 2b trial to reflect the endpoints used in the Phase 3 trials, after the ongoing qualitative study is completed and before the Phase 2b at-home trial is initiated, we plan to request another Type C meeting to obtain the FDA's guidance on endpoints for our Phase 2b and Phase 3 clinical trials, including whether the FDA agrees that our proposed PRO instruments are content valid for the target population. The timing of when we initiate the Phase 2b at-home trial will be influenced by such guidance.

We plan to leverage the existing data on sildenafil and the established safety profile of the Viagra® brand to pursue the FDA's 505(b)(2) pathway for approval of Sildenafil Cream, 3.6% in the U.S. If approved, Sildenafil Cream, 3.6% could be the first FDA-approved FSAD treatment option for women.

DARE-HRT1

In April 2018, we announced that we entered into an exclusive, global license with Juniper Pharmaceuticals, Inc., or Juniper, for its novel intravaginal ring, or IVR, technology. Our license covers all rings that were in development by Juniper, as well as additional applications of the IVR technology platform in other therapeutic areas. Unlike other vaginal rings, this IVR technology is designed to release drugs via a solid ethylene vinyl acetate polymer matrix without the need for a membrane or reservoir to contain the active drug or control the release, allowing for sustained drug delivery over time periods ranging from weeks to months.

DARE-HRT1 (formerly known as JNP-0201) is the first product candidate based on Juniper's IVR technology that we are advancing into clinical development. DARE-HRT1 is a unique IVR that combines bio-identical estradiol and progesterone to treat vasomotor symptoms (VMS) associated with menopause as part of a hormone replacement therapy regimen. Hormone replacement therapy, or HRT, is considered the most effective treatment for VMS and the genitourinary syndrome of menopause and has been shown to prevent bone loss and fracture.

In 2019, we plan to conduct a Phase 1 open-label, three-arm, parallel group study in approximately 30 healthy post-menopausal women to evaluate the pharmacokinetics, or PK, and safety of DARE-HRT1. The primary objectives of the proposed study are to describe the PK parameters of two different dose combinations (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) over 28 days, and to identify the steady state PK of each dose combination after 28 days. We expect to report topline results of this clinical study in 2020.

We plan to leverage the existing data and established safety profile of the active ingredients in DARE-HRT1, estradiol and progesterone, to utilize the FDA's 505(b)(2) pathway for approval of DARE-HRT1 as hormone replacement therapy following menopause in the U.S.

Sales and Marketing

We currently have no formal internal marketing or sales infrastructure or capabilities. If and when our product candidates are approved, we expect to enter into agreements with companies with established marketing and sales capabilities in women's health in order to supplement our internal marketing or sales efforts.

Manufacturing

We rely on third parties to manufacture our clinical trial materials and supplies and, if our product candidates receive regulatory approval, we expect to rely on third-party manufacturers to produce commercial quantities of our products.

License Agreements

ADVA-Tec License Agreement

In March 2017, we entered into a license agreement, or the ADVA-Tec License Agreement, with ADVA-Tec, Inc. under which we were granted an exclusive license under ADVA-Tec's intellectual property rights to develop and commercialize Ovaprene for human contraceptive use worldwide. ADVA-Tec and its affiliates own issued patents or patent applications covering Ovaprene, and control proprietary trade secrets covering the manufacture of Ovaprene. As of March 29, 2019, this patent portfolio includes nine issued U.S. patents and one pending U.S. patent application, and 59 granted patents and four pending patent applications in other major markets, all of which are exclusively licensed to us for all uses of Ovaprene as a human contraceptive device. Under the ADVA-Tec License Agreement, we have a right of first refusal to license these patents and patent applications for additional indications.

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

Research and Development. ADVA-Tec will conduct certain research and development work as necessary to allow us to seek a PMA from the FDA and will provide us with clinical supplies of Ovaprene for clinical and commercial use on commercially reasonable terms. We must use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, and $5 million in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

Milestone and Royalty Payments. We will pay to ADVA-Tec: (1) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones; and (2) up to $20 million in the aggregate based on the achievement of certain worldwide net sales milestones. The development and regulatory milestones include: the completion of a successful postcoital clinical study, which is required before we can commence a Phase 3 pivotal human clinical trial; the FDA's approval to commence a Phase 3 pivotal human clinical trial; successful completion of such Phase 3 pivotal human clinical trial; the FDA's acceptance of a PMA filing for Ovaprene; the FDA's approval of the PMA for Ovaprene; 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. Because these milestone payments depend upon the successful progress of our product development programs, we cannot estimate with certainty when these payments will occur, if ever.

Royalty Payments. After the commercial launch of Ovaprene, we will pay to ADVA-Tec royalties based on aggregate annual net sales of Ovaprene in specified regions at a royalty rate that will vary between 1% and 10% and will increase based on various net sales thresholds.

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

SST License and Collaboration Agreement

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

pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen, or the Licensed Products.

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

Invention Ownership. We retain rights to inventions made by our employees, SST retains rights to inventions made by its employees, and each party owns a 50% undivided interest in all joint inventions.

Joint Development Committee. The parties will collaborate through a joint development committee that will determine the strategic objectives for, and generally oversee, the development efforts of both parties under the SST License Agreement.

Development. We must use commercially reasonable efforts to develop the Licensed Products in the Field of Use in accordance with a development plan in the SST License Agreement, and to commercialize the Licensed Products in the Field of Use. We are responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it must perform under the SST License Agreement.

Royalty Payments. SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

Milestone Payments. SST will be eligible to receive payments (1) ranging from $0.5 million to $18.0 million in the aggregate upon achieving certain clinical and regulatory milestones in the U.S. and worldwide, and (2) between $10.0 million to $100 million in the aggregate upon achieving certain commercial sales milestones. If we enter into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST.

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

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

Orbis Development and Option Agreement

In March 2018, we entered into an exclusive development and option agreement, or the Orbis Agreement, with Orbis Biosciences for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). Under the Orbis Agreement, we paid Orbis $300,000 to conduct the first stage of development work, Stage 1, as follows: $150,000 upon signing the Orbis Agreement, $75,000 at the 50% completion point, not later than 6 months following the date the Orbis Agreement was signed (which we paid in September 2018), and $75,000 upon delivery by Orbis of the 6-month batch, not later than 11 months following the date the Orbis Agreement was signed (which we paid in January 2019). Upon Orbis successfully completing Stage 1 of the development program and achieving the predetermined target milestones for Stage 1, we will have 90 days to instruct Orbis whether to commence the second stage of development work, Stage 2. Should we execute our option to proceed to Stage 2, we will provide additional funding to Orbis for such activities.

Pre-clinical studies for the 6- and 12-month formulations have been completed, including establishing pharmacokinetics and pharmacodynamics profiles. The collaboration with Orbis will continue to advance the program through formulation optimization with the goal of achieving sustained release over the target time period.

The Orbis Agreement provides us with an option to enter into a license agreement for ORB-204 and ORB-214 should development efforts be successful.

Juniper Pharmaceuticals License Agreement

In April 2018, we entered into an Exclusive License Agreement, or the Juniper License Agreement, with Juniper Pharmaceuticals, Inc., under which Juniper granted us (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Juniper, to make, have made, use, have used, sell, have sold, import and have imported products and processes; and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Juniper to make, have made, use, have used, sell, have sold, import and have imported products and processes. We are entitled to sublicense the rights granted to it under the Juniper License Agreement.

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

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

Annual Maintenance Fee. We will pay an annual license maintenance fee to Juniper on each anniversary of the date of the Juniper License Agreement, the amount of which will be $50,000 for the first two years and $100,000 thereafter, and which will be creditable against royalties and other payments due to Juniper in the same calendar year but may not be carried forward to any other year.

Milestone Payments. We must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the Juniper License Agreement.

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

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

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

Hammock/MilanaPharm Assignment and License Agreement

On December 5, 2018, we entered into (a) an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and (b) a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, we acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In DARE-BV1, this proprietary technology is formulated with clindamycin, an antibiotic used to treat certain bacterial infections including BV, and has been engineered to produce a dual release pattern after vaginal application, providing maximum duration of exposure to clindamycin at the site of infection.

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

License Fees. We paid $25,000 to MilanaPharm in connection with the execution of the License Amendment and must pay $200,000 to MilanaPharm (in our discretion, either in cash or with shares of our common stock) within 15 days of the first to occur of December 5, 2019 or the closing of an equity financing in which we raise aggregate proceeds of at least $10 million.

Milestone Payments. We will pay to MilanaPharm: (1) up to $300,000 in the aggregate upon achievement of certain clinical and regulatory development milestones; and (2) up to $1.75 million in the aggregate upon achieving certain commercial sales milestones.

Foreign Sublicense Income. We will pay MilanaPharm a low double-digit percentage of all income received by us or our affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions.

Royalty Payments. During the royalty term, we will pay MilanaPharm high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes. The royalty term, which is determined on a country-by-country basis and licensed product-by-product basis (or process-by-process basis), begins with the first commercial sale of a licensed product or process in a country and terminates on the latest of (1) the expiration date of the last valid claim of the licensed patent rights that cover the method of use of such product or process in such country, or (2) 10 years following the first commercial sale of such product or process in such country. Royalty payments are subject to reduction in certain circumstances, including as a result of generic competition, patent prosecution expenses incurred by us, or payments to third parties for rights or know-how required for us to exercise the licenses granted to it under the MilanaPharm License Agreement or that are strategically important or could add value to a licensed product or process in a manner expected to materially generate or increase sales.

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

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

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

fail to reasonably demonstrate a strategic justification for the discontinuation and failure to resume to MilanaPharm, and (D) MilanaPharm gives 90 days' notice to us.

The following is a summary of other terms of the Assignment Agreement:

Assignment; Technology Transfer. Hammock assigned and transferred to us all of its right, title and interest in and to the MilanaPharm License Agreement and agreed to cooperate to transfer to us all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan to be agreed upon by the parties, with a goal for us to independently practice the licensed intellectual property as soon as commercially practical in order to develop and commercialize the licensed products and processes.

Fees. We paid $250,000 to Hammock in connection with the execution of the Assignment Agreement and must pay $250,000 to Hammock (in our discretion, either in cash or with shares of our common stock) within 15 days of the first to occur of December 5, 2019 or the closing of an equity financing in which we raise aggregate proceeds of at least $10 million.

Milestone Payments. We will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones.

Term. The Assignment Agreement will terminate upon the later of (1) completion of the parties' technology transfer plan, and (2) payment to Hammock of the last of the payments described above, including the milestone payments.

Intellectual Property

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

Patents

The medical device and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any claim relating to infringement of third party patents that is successfully asserted against us or our licensors may require us to pay substantial damages or may limit our or our licensors' ability to rely on such patent protection. Any third party claim successfully alleging the invalidity or unenforceability of the patents may also limit our or our licensors' ability to rely on such patent protection. Even if we, or our licensors were to prevail in any such action, any litigation could be costly and time-consuming and would divert the attention of management and key personnel from our business operations. Also, if our product candidates or any future products are found to infringe the patents of others, our development, manufacture, and sale of these potential products could be severely restricted or prohibited. In addition, there can be no assurance that any patent applications filed by us or our licensors will result in the grant of a patent either in the United States or elsewhere, or that any patents granted will be valid and enforceable, or that any patents will provide a competitive advantage or afford protection against competitors with similar technologies. Because of the importance of the patents underlying our product candidates, our business and our prospects may be harmed if we fail to maintain existing or obtain new patent rights or if we and our licensors fail to protect key intellectual property rights.

Under the terms of the ADVA-Tec License Agreement, we are the exclusive licensee of nine granted U.S. patents and one pending U.S. patent application, and 59 granted patents and four pending patent applications in other major markets. Three of the patents that are particularly important to the protection of Ovaprene have terms until August 2028.

Under the terms of the SST license Agreement, we are the exclusive licensee in the Field of Use of sixteen issued patents worldwide (seven U.S. patents and nine foreign patents), along with one pending U.S. patent application and seven pending worldwide patent applications, including two that have received Notices of Allowability. The issued U.S. patents have a patent term until June 2029, including any patent term adjustment, and may be eligible for patent exclusivity under the Hatch-Waxman Act.

Under the terms of the Juniper License Agreement, we are the exclusive licensee of four issued U.S. patents with patent terms until April 2024, November 2024, and September 2027, including patent term adjustment, and six issued foreign patents with patent terms until April 2024. We have one pending Patent Cooperation Treaty application that will have national phase filings beginning in November 2019.

Under the terms of the Assignment Agreement with Hammock Pharmaceuticals, Inc. and the License Amendment with TriLogic Pharma, LLC and MilanaPharm, LLC, we are the exclusive licensee of three issued U.S. Patents, two with patent terms until December 2028 and one with a patent term until June 2031 not including any patent term adjustment, and five foreign patents that have patent terms until December 2028. In addition, we have rights to four pending foreign patent applications and two pending U.S patent applications. If issued the patent term for these patents would be between 2036 and 2037 not including any patent term adjustment.

When we acquired Pear Tree Pharmaceuticals, Inc. in April 2018, we obtained the rights to three U.S. patents and one Japan patent. The patent term for two of the U.S. patents will expire in June 2027 and one will expire in May 2035 not including any patent term adjustment. The Japan patent has a term until June 2027.

We also rely upon trade secret rights to protect our product candidates as well as other technologies that may be used to discover, validate and commercialize our current or any future product candidates. We presently seek protection, in part, through confidentiality and proprietary information agreements.

Trademarks

We hold a domestic registration for the trademark Daré Bioscience. In accordance with the terms of the ADVA-Tec License Agreement, we are the exclusive licensee of the Ovaprene registered trademark.

Market Access

We intend to create a comprehensive global commercialization strategy in combination with established pharmaceutical partners and regional distributors.

Pre-Clinical Programs

In addition to our clinical-stage product candidates, we have licenses or other rights to the following pre-clinical stage product candidates in women's health that meet our selection criteria of technology or product candidates with potential to expand options and improve outcomes, and that are easy and convenient to use:

- DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel;
- ORB-204 and ORB-214, 6-month and 12-month formulations of injectable etonogestrel for contraception;
- DARE-FRT1 (formerly JNP-0301), an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an in *vitro fertilization*, or IVF, treatment plan;
- DARE-OAB1 (formerly JNP-0101), an intravaginal ring containing oxybutynin for the treatment of overactive bladder; and
- DARE-VVA1 (formerly PT-101), a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone-receptor positive breast cancer

We may seek to acquire or license additional product candidates or technology to continue building a robust product pipeline over time.

Research and Development

Our research and development expenses during 2018 consisted primarily of the costs associated with building our portfolio of product candidates and with product development activities related to Ovaprene and Sildenafil Cream 3.6%, and to a lesser extent, DARE-BV1 and DARE-HRT1. Costs associated with our product development activities include the costs of: 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 associated with activities performed by us and our partners and generally benefit multiple programs. See PART II—Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations," below for more information regarding our research and development expenses.

Competition

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology and medical device) are highly competitive and subject to rapid and significant change. We may not compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have greater clinical, regulatory, manufacturing, marketing, distribution, compliance and financial resources and experience than we do. See “ITEM 1A. RISK FACTORS—Risks Related to our Business—We face intense competition from other medical device, biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively,” below.

Over the longer term, our ability, independently or otherwise, to successfully develop, manufacture, market, distribute and sell any approved products, expand their usage or bring additional new products to the marketplace will depend on many factors, including, but not limited to, FDA and foreign regulatory agency approval of new products and of new indications for existing products, the efficacy and safety of our products (alone and relative to other treatment options), the degree of patent or other protection afforded to particular products, and reimbursement for use of those products.

Many other organizations are developing drug products and other therapies intended to treat the same diseases and conditions for which our product candidates are in development, and the success of others may render potential application of our product candidates obsolete or noncompetitive, even prior to completion of its development.

Suppliers

We rely on third parties to produce all of our clinical supplies, and we expect to continue to do so in the foreseeable future. In many cases the parties responsible for the finished product must also rely on third parties to provide raw materials, drugs and other materials required to produce a finished product and to produce the quantities needed. See "ITEM 1A. Risk Factors—Risks Related to our Business—Our success relies on third party suppliers, manufacturers and distributors, including multiple single source suppliers and manufacturers. We have no internal sales, marketing or distribution capabilities. Any failure by such third parties could negatively impact our business and our ability to develop and market any approved products," below.

DARE-BV1. We will be responsible for contracting with suppliers to produce our hydrogel formulation of clindamycin phosphate 2%. We expect the quantities of DARE-BV1 required to meet our foreseeable needs will generally be available and that multiple supply sources will be readily available.

Ovaprene. ADVA-Tec will be responsible for all activities related to process development and scale up of Ovaprene manufacturing. Further, either directly or via a contract manufacturing organization, ADVA-Tec will be responsible for Ovaprene clinical and commercial supply. For some key raw materials and components of Ovaprene, there is only a single source of supply, and alternate supply sources may not be readily available.

Sildenafil Cream, 3.6%. SST will be responsible for obtaining supplies of Sildenafil Cream, 3.6% for the Phase 2 clinical studies expected to be conducted in the United States. Thereafter, we will be responsible for obtaining pre-clinical, clinical and commercial supplies of Sildenafil Cream, 3.6%. We expect the quantities of Sildenafil Cream, 3.6% required to meet our foreseeable needs will generally be available and that multiple supply sources will be readily available.

DARE-HRT1. We will be responsible for contracting with manufacturers and suppliers to produce our intravaginal rings. We expect that the quantities of DARE-HRT1 required to meet our foreseeable needs will generally be available and that multiple supply sources will be readily available.

Government Regulation

Governmental authorities in the U.S. and other countries extensively regulate the testing, manufacturing, labeling and packaging, storage, recordkeeping, advertising, promotion, import, export, marketing, and distribution, among other things, of pharmaceutical, medical device, and combination products. In the U.S., the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and other federal statutes and regulations, subject pharmaceutical and other regulated products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may send us a warning letter, refuse to approve our marketing applications or allow us to manufacture or market our products, our products may be seized, the government may seek injunctions against us, and we may be criminally prosecuted.

We and our third-party manufacturers, distributors and contract research organizations, or CROs, may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act, the Health Insurance Portability and Accountability Act, privacy laws and import, export and customs regulations, as well as the laws and regulations of other countries.

FDA Approval Process for Prescription Drugs

To obtain approval of a new drug product from the FDA, we must, among other requirements, submit data supporting its safety and efficacy, as well as detailed information on the manufacture and composition of the drug and proposed product labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our product candidates.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves some or all of the following key steps:

- completion of nonclinical studies performed in compliance with FDA regulations;
- design of a clinical protocol and its submission to the FDA as part of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- submission of an NDA after completion of pivotal clinical trials and FDA acceptance of that NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current good manufacturing practices, or cGMP;
- possible inspection of selected clinical sites to confirm compliance with good clinical practices, or GCP, requirements and data integrity; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug product in the U.S.

The clinical investigation of an investigational new drug is divided into three phases that typically are conducted sequentially but may overlap. The three phases are as follows:

Phase 1. Phase 1 includes initial clinical trials introducing an investigational new drug into humans and may be conducted in subjects with the target disease or normal volunteers. These trials are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

Phase 2. Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the drug for a particular indication or indications in subjects with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 trials are typically well controlled, closely monitored, and conducted in a relatively small number of subjects.

Phase 3. Phase 3 trials are typically large trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling and product marketing approval. Phase 3 trials usually are conducted at geographically dispersed clinical study sites.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA.

A pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

Clinical trials must be conducted in accordance with the FDA's GCP requirements. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, known as a "clinical hold," or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects are being exposed to an unacceptable health risk. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical study subjects. An institutional review board, or IRB, is responsible for ensuring that human subjects in clinical studies are protected from inappropriate study risks. An IRB must approve the clinical trial design and process for obtaining subject informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with GCP or the IRB's requirements.

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA increases as clinical development progresses. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including API) are subject to requirements that drugs be manufactured, packaged, tested, and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more indications, together with payment of a significant user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the product candidate's chemistry, manufacturing, and controls, or CMC, and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

Most innovative drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDCA, commonly referred to as a "full NDA." Another alternative is a special type of NDA submitted under Section 505(b)(2) of the FDCA, commonly referred to as a 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products.

Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate or reduce the need to conduct certain pre-clinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

The FDA reviews all NDAs, whether 505(b)(1) or 505(b)2 applications, submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA has 60 days after submission of an NDA to conduct an initial review to determine whether it is sufficient to accept for filing.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA sets a goal date by which it plans to complete its review. For a standard review, this goal date typically is ten months from the date of submission of the NDA application. If the NDA application relates to an unmet medical need in a serious or life-threatening indication and is designated for priority review, the FDA's goal date typically is six (6) months from the date of NDA submission. However, PDUFA goal dates are not legal mandates and FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests, or the NDA sponsor otherwise provides, additional information or clarification regarding information already provided in the NDA. As a result, the NDA review process can be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee of independent experts for a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

Data from clinical trials are not always conclusive, and the FDA or its advisory committee may interpret data differently than the NDA sponsor.

After evaluating the NDA and inspecting manufacturing facilities where the drug product or its API will be produced, the FDA will either approve commercial marketing of the drug product for specific indications of use or issue a complete response letter, or CRL, indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the CRL requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA also may condition drug approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval.

If the FDA approves any of our product candidates, we will be required to comply with a number of ongoing post-marketing regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, and to comply with requirements concerning advertising and promotional labeling for any of our prescription drug products, including submitting all of our advertising and promotional labeling to the FDA at the time those are publicly disseminated. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we typically will need FDA approval before the change can be implemented. For example, if we change the manufacturer of a product or its API, the FDA may require stability or other data such as a bioequivalence study from the new manufacturer to assure the agency that the prior and new formulations are interchangeable, which data will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. Moreover, although physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved pursuant to an NDA. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled clinical trials to demonstrate the product's safety and efficacy in the new indication. Even if such trials are conducted, the FDA may not approve any expansion of the labeled indications for use in a timely fashion, or at all.

We rely on third parties for the manufacture of our clinical trial material and we expect to rely on third-party manufacturers to produce commercial quantities of our drugs and devices, should they receive regulatory approval in the future. Future FDA, state, or foreign governmental agency inspections may identify compliance issues at these third-party facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated, or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Many of the foregoing could limit the commercial value of a product or require us to commit substantial additional resources in connection with the approval of an investigational drug. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Pharmaceutical Pricing and Reimbursement

Sales of our drug products, if approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health care programs, private health insurers, managed health care providers, and other organizations. These third-party payors are increasingly challenging drug prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approval as a benefit under their plans or, even if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage and payment. Sales of any products for which we obtain marketing approval will depend in part on coverage and adequate payment from third-party payors. There is no uniform policy requirement for coverage and

reimbursement for drug products among third-party payors in the United States; therefore coverage and reimbursement for drug products can differ significantly from payor to payor. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payor will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for health care providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use.

Additionally, the containment of health care costs has become a priority of federal and state governments and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that federal, state and local governments in the U.S. will continue to consider legislation directed at lowering the total cost of health care. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, has had and is expected to continue to have a significant impact on the health care industry. The ACA, among other things, imposes a significant annual fee on certain companies that manufacture or import branded prescription drug products. The ACA also increased the Medicaid rebate rate and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations. The ACA also expanded the 340B drug discount program (excluding orphan drugs), including a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, and revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of the Medicaid drug rebates paid to states. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against health care fraud and abuse, add new transparency requirements for the health care industry, impose new taxes and fees on pharmaceutical manufacturers, and impose additional health policy reforms, any or all of which may affect our business. Since its enactment there have been judicial and congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Certain provisions of the ACA are not yet, or have only recently become, effective, and others have been temporarily suspended, but the ACA is likely to continue the downward pressure on pharmaceutical pricing and may also increase our regulatory burdens and operating costs.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, which went into effect in 2013 and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken, Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding. Strong, partisan disagreement in Congress has prevented implementation of various ACA provisions, while the Trump Administration has made repeal of the ACA a priority. One of the first executive orders of the Trump administration granted federal agencies broad powers to unwind regulations under the ACA. On January 11, 2017, the Senate voted to approve a “budget blueprint” allowing Republicans to repeal parts of the law while avoiding Democrat filibuster. The “Obamacare Repeal Resolution” passed 51-48. Certain legislators are continuing their efforts to repeal the ACA, although there is little clarity on how such a repeal would be implemented and what an ACA replacement might look like. For the immediate future, there is significant uncertainty regarding the health care, health care coverage and health care insurance markets.

It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidates or what actions federal, state, or commercial payors for pharmaceutical products may take in response to any such health care reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates.

FDA Approval Process for Combination Products and Medical Devices

A combination product is a product composed of a combination of two or more FDA-regulated product components or products, e.g., drug-device or biologic-device. A combination product can take a variety of forms, such as a single entity made by physically or chemically combining components, or a single unit made of separately packaged

products. Each combination product is assigned a lead FDA Center, which has jurisdiction for the premarket review and regulation, based on which constituent part of the combination product provides the primary mode of action, i.e., the mode of action expected to make the greatest contribution to the overall intended therapeutic effect of the product. If the classification as a combination product or the lead Center assignment is unclear or in dispute, a sponsor may request a meeting, submit a Request for Designation or RFD, and the FDA will issue a designation letter within 60 calendar days of the filing of the RFD. Depending on the type of combination product, the FDA may require a single application for approval, clearance, or licensure of the combination product, or separate applications for the constituent parts. During the review of marketing applications, the lead Center may consult or collaborate with other FDA Centers.

In 2017, the FDA released final documents addressing the application of cGMP requirements and classification issues relating to combination products. The 21st Century Cures Act, or the Cures Act, which became law in December 2016 and, among other things, amended provisions of the FDCA, sets forth a number of provisions pertaining to combination products, such as procedures for negotiating disagreements between sponsors and the FDA and requirements intended to streamline FDA premarket reviews of combination products that contain an already-approved component. For drug-device combination products, comprised of an FDA-approved drug and device primary mode of action, the Cures Act applies Hatch-Waxman requirements to the premarket review process such that a patent dispute regarding the listed drug may result in the delay of the 510(k) clearance or PMA approval of the combination product. Furthermore, the Cures Act applies exclusivity provisions (e.g., new chemical entity and orphan drug exclusivities) to the device clearance and approval process for combination products with a device primary mode of action.

Because the FDA has different centers responsible for assessing and approving devices, drugs, and biologics, the FDA's response to an RFD submitted by a sponsor will assign a lead center for the combination product. The CDRH has oversight responsibility for medical devices, while the Center for Drug Evaluation and Research, or CDER, has responsibility for drug products. Because combination products involve components that would normally be regulated under different types of regulatory regimes, and frequently by different FDA Centers, they raise challenging regulatory, policy, and review management challenges. Differences in regulatory pathways for each component can impact the regulatory processes for all aspects of product development and management, including pre-clinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.

The development and approval process for combination products designated as having a drug-primary mode of action and assigned to CDER generally will follow the procedures set forth above for pharmaceutical products. Similarly, medical devices and combination products with a device-primary mode of action may also be subject to FDA approval and extensive regulation under the FDCA. Medical devices are classified into one of three classes: Class I, Class II, or Class III. A higher class indicates a greater degree of risk associated with the device and a greater amount of control needed to ensure safety and effectiveness.

All devices, unless exempt by FDA regulation, must adhere to a set of general controls, including compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, which sets forth good manufacturing practice requirements for medical devices, including stringent design controls; facility registration and product listing; reporting of adverse medical events; truthful and non-misleading labeling; and promotion of the device consistent with its cleared or approved intended uses. Class II devices are subject to additional special controls and may require FDA clearance of a premarket notification (510(k)). Class III devices, which involve those posing the greatest health risk, require approval of a premarket approval application, or PMA.

Most Class I devices are exempt from FDA premarket review or approval. Class II devices, with some exceptions, must be "cleared" by the FDA through the 510(k) process, which requires a company to show that the device is "substantially equivalent" to certain devices already on the market. Class III devices, again with some exceptions, must be approved through a PMA. A PMA generally requires data from clinical trials that establish the safety and effectiveness of the device. A 510(k) application also sometimes requires clinical data. The Cures Act requires the FDA to establish a program that would expedite access to devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, for which no approved or cleared treatment exists or which offer significant advantages over existing approved or cleared alternatives; in 2018, the FDA published its final guidance on this "breakthrough" devices pathway.

Clinical trials for medical devices are subject to similar requirements as clinical trials with pharmaceutical products. Clinical trials involving significant risk devices (e.g., devices that present a potential for serious risk to the health, safety, or welfare of human subjects) are required to obtain both FDA approval of an investigational device exemption, or IDE, application and IRB approval before study initiation; clinical trials involving non-significant risk devices are not required to submit an IDE for FDA approval but must obtain IRB approval before study initiation.

The FDA has broad regulatory and enforcement powers with respect to medical devices, similar to those for pharmaceutical products. The FDA requires medical device manufacturers to comply with detailed requirements regarding device design and manufacturing practices, labeling and promotion, record keeping, and adverse event reporting. As with pharmaceutical products, states also impose regulatory requirements on medical device manufacturers and distributors. Failure to comply with the applicable federal or state requirements could result in, among other things: (1) fines, injunctions, and civil penalties; (2) recall or seizure of products; (3) operating restrictions, partial suspension or total shutdown of manufacturing; (4) refusing requests for approval of new products; (5) withdrawing approvals already granted; and (6) criminal prosecution.

The FDA also administers certain controls over the import and export of medical devices to and from the United States. Additionally, each foreign country subjects medical devices to its own regulatory requirements. In the European Union, a single regulatory approval process has been created, and approval is represented by the CE Mark, which requires conformity to a Medical Device Regulation, or MDR, that went into effect in 2017 and imposed significant new requirements.

Other Health Care Laws and Compliance Requirements

In addition to FDA requirements, several other types of state and federal laws apply and will apply to our operations. These laws include, among others, health care information and data privacy protection laws, transparency laws, and fraud and abuse laws, such as anti-kickback and false claims laws.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item, good, facility or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws and civil monetary penalties laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Pharmaceutical and other health care companies have been prosecuted under these laws for, among other things, allegedly promoting their products for uses for which they were not approved and causing the submission of claims for payment for such use under federal health care programs.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, imposes obligations, including mandatory contractual terms, on certain types of individuals and entities, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The ACA also includes federal transparency requirements that apply to certain manufacturers of drug products, medical devices, biologics and medical supplies and require them to annually report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. Compliance with such "Sunshine Act" reporting requirements may be costly for us once we have a drug product in commercial distribution and it is reimbursed by Medicaid.

The majority of states also have statutes or regulations similar to the aforementioned federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. We may be subject to state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In addition, we may be subject to reporting requirements under state transparency laws, as well as state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to health care providers and entities.

Because we intend to commercialize products that could be reimbursed under federal and other governmental health care programs, we expect to develop a compliance program that establishes internal controls to

facilitate adherence to the rules and health care program requirements. Although compliance programs and adherence thereto may mitigate the risk of violation of and subsequent investigation and prosecution for violations of the laws described above, the risks cannot be eliminated entirely. In addition, due to the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state health care programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and/or the curtailment or restructuring of our operations.

Government Regulation Outside the U.S.

In addition to regulations in the U.S., we may be subject to a variety of regulations in foreign jurisdictions that govern, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical trials or marketing and sale of the product in those countries. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above. Some foreign jurisdictions have a drug product approval process similar to that in the U.S., which requires the submission of a clinical trial application much like the IND prior to the commencement of clinical studies. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval of a product candidate under European Union regulatory systems, we would be required to submit a Marketing Authorisation Application, which is similar to the NDA, except that, among other things, there are country-specific document requirements. For countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. And, some nations may not accept clinical studies performed for U.S. approval to support approval in their countries or require that additional studies be performed on natives of their countries. In addition, regulatory approval of prices is required in most countries other than the U.S. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or any future partner of ours. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Employees

As of December 31, 2018, we had nine full-time and five part-time employees, six in research and development and seven in general and administrative. Given the differing characteristics of our product candidates, our approach is to engage consultants with experience in varying specialties to help us develop such candidates. Our numerous consultants serve as an extension to our full-time employee base. We believe this approach will enable us to access the expertise needed in a cost-efficient manner and without the need to expand the number of full-time employees and their associated costs.

Company Information

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

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

On July 20, 2017, we effected a 1-for-10 reverse stock split of our common stock. All share and per share amounts of common stock, options and warrants in this report, including those amounts included in the

accompanying consolidated financial statements, have been restated for all periods to give retroactive effect to the reverse stock split.

Available Information

Our website is located at *http://www.darebioscience.com*. Information found on our website is not incorporated by reference into this report. We make our filings with the U.S. Securities and Exchange Commission, or SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments and exhibits to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, available free of charge on or through our website, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings at *http://www.sec.gov*.

ITEM 1A. RISK FACTORS

Investment in our securities involves a high degree of risk and uncertainty. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this report and our other public filings, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

Risks Related to Our Business

We will need to raise additional capital to continue our operations.

We expect that our net losses will continue for the foreseeable future as we develop our existing product candidates and seek to acquire, license or develop additional product candidates. Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidates towards or through clinical trials. Our ability to continue as a going concern depends on our ability to raise additional capital through financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements, to successfully execute our current operating plan and to continue the development of our current product candidates.

Our capital needs have been and will continue to depend highly on the product development programs we choose to pursue, the progress of these programs, including the number, size, timing, rate of patient recruitment, duration of patient treatment and follow-up and the results of our clinical trials and pre-clinical studies, the cost and timing of development and supply of material for our clinical trials and pre-clinical studies, the cost, timing and outcomes of regulatory submissions and decisions regarding a potential approval for any one or more of our current or future product candidates we may choose to develop, and the terms of our contracts with service providers and license partners. In addition, the development of our clinical-stage candidates, DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, and DARE-HRT1, and the advancement of our pre-clinical product candidates will depend on results of ongoing and upcoming clinical trials and our financial resources at the time of such results. Should our product development efforts succeed, we will need to develop a commercialization plan for each product developed, which would also require significant resources to develop and implement.

At December 31, 2018, our cash and cash equivalents were $6.8 million and our accumulated deficit was approximately $29.0 million. We expect negative cash flows from our operations to continue for the foreseeable future. We believe our existing cash resources will be sufficient to fund planned operations into the third quarter of 2019. For the foreseeable future, our ability to continue our operations will depend on our ability to obtain additional capital. We incurred a net loss of approximately $16.7 million for the year ended December 31, 2018, which included a non-cash impairment charge to goodwill of approximately $5.2 million. We may never become profitable.

For the reasons stated above, this report includes disclosures and an opinion from our independent registered public accounting firm stating that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2018 were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

If we raise capital through collaborations, strategic alliances or other similar types of arrangements, we may have to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates we would otherwise seek to develop or commercialize. See also “—We expect to be heavily reliant on our ability to raise capital through capital market transactions. Due to our small public float, low market capitalization, limited operating history and lack of revenue, it may be difficult and expensive for us to raise additional funds,” below. There can be no assurance that we can raise capital when needed or on terms favorable to us and our stockholders. If we cannot raise capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our development programs, reduce expenses or cease operations, any of which would have a significant negative impact on our prospects and financial condition, as well as the trading price of our common stock. See also "Our ability to raise capital may be limited by applicable laws and regulations," below. Moreover, if we are unable to obtain additional funds on a timely basis, there will be an increased risk of insolvency and up to a total loss of investment by our stockholders.

We have a limited operating history, have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources, makes it difficult to assess our prospects. We must raise additional capital to finance our operations and remain a going concern.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which to evaluate our business and prospects. Drug development is a highly speculative undertaking and involves substantial risk. To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue. We have not been profitable since we commenced operations and may never achieve profitability. We have devoted significant resources to acquiring our portfolio of product candidates and to research and development activities for our product candidates. Since inception, we have incurred significant operating losses. See also "We will need to raise additional capital to continue our operations," above.

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

In January and February 2018, we raised approximately $11.3 million in gross proceeds through the sale of equity securities under a Form S-3 “shelf” registration statement. Using a shelf registration statement to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. We currently have a shelf registration statement effective. However, our ability to raise capital under this registration statement may be limited by, among other things, current and future SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. For example, the market value of our outstanding shares of common stock held by non-affiliates, or public float, was less than $75.0 million at the time we filed our shelf registration statement and has been less than $75.0 million since such time. As such, we are subject to the "baby shelf rules," which means that the aggregate market value of securities sold by us or on our behalf pursuant to Instruction I.B.6. of Form S-3 during the 12 calendar months immediately prior to, and including the intended sale is limited to no more than one-third of the aggregate market value of our public float. Our public float for this purpose is calculated by multiplying (a) the number of shares of common stock in our public float by (b) the highest price at which the common stock was last sold as of a date within 60 days prior to the date of the intended sale. The highest price at which our common stock last sold as of a date within 60 days of March 29, 2019 was $2.10, and based on that price, our public float would be approximately $19.2 million, one-third of which is $6.4 million. No securities have been sold by us or on our behalf pursuant to Instruction I.B.6. of Form S-3 during the 12 calendar months ending March 29, 2019. If our ability to offer securities under our shelf registration statement is limited, we may choose to conduct such an offering under an exemption from registration under the Securities Act of 1933 or under a Form S-1 registration statement. We would expect either alternative to increase the cost of raising additional capital relative to using our shelf registration statement.

In addition, under SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to use a Form S-3 registration statement (1) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or a re-evaluation date, whichever is later, and (2) to register the resale of our securities by persons other than us (i.e., a resale offering). While our common stock is currently listed on the Nasdaq Capital Market, there can be no assurance that we can maintain such listing. See, “—Risks Related to Our Securities-There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market,” below.

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

Obtaining stockholder approval is a costly and time-consuming process. If we must obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition,

seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our business plan, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

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

Our current financial and technical resources are limited and not sufficient to develop all of the product candidates to which we hold licenses or options to license. This may affect the development efforts of our key portfolio candidates and any future candidates we may choose to develop. Due to our limited resources, we may be required to curtail clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates, or product candidates that we may in the future choose to develop, through the regulatory and development processes. We may make incorrect determinations with regard to the indications and clinical trials on which to focus our resources. The decisions to allocate our research, management and financial resources toward particular indications may not lead to positive clinical milestones or to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also cause us to miss valuable opportunities, including the potential for some of our product candidates to be first-in-category products.

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

We are heavily reliant on our ability to raise additional capital by selling shares of our common stock or securities linked to our common stock. Our ability to raise capital will depend on several factors, many of which may not be favorable for raising capital, including the low trading volume and volatile trading price of our common stock, our low public float, our potential inability to continue to satisfy the listing requirements of the Nasdaq Capital Market, unfavorable market conditions or other market factors outside of our control, and the risk factors described elsewhere in this report, including those related to warrants we issued in February 2018. See "—Our ability to raise capital may be limited by laws and regulations," above, and the risk factors under "—Risks Related to Our Securities," below. Even if we are able to raise additional capital, it will likely be dilutive to existing stockholders and the cost of such capital may be substantial and may be more expensive than the cost of capital for larger public companies. The terms of any funding we obtain may not be favorable to us and may be highly dilutive to our stockholders, and debt financing, if available, may involve restrictive covenants. There can be no assurance that we can raise additional capital when needed. Failing to raise additional capital when needed would have a material adverse effect on our business.

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

Our business strategy is to license or otherwise acquire the rights to differentiated health product candidates primarily in the areas of contraception, vaginal health, sexual health, and fertility, and to take those candidates through advanced stages of clinical development and regulatory approval. Advancing product candidates through late stages of clinical development will require substantial investment. We currently do not have the capital necessary to advance the product candidates to which we hold licenses and options to license. Executing our business strategy requires us to obtain additional capital to license or otherwise acquire rights to additional product candidates to grow and advance our portfolio and to take our current and future product candidates through clinical development and eventually to commercialization or strategic partnership. Such capital may not be available to us, or even it is, the cost of such capital may be high. See "—We will need to raise additional capital to continue our operations," above. Should we add additional product candidates to our portfolio, should our existing product candidates require testing or other capital -intensive procedures we did not anticipate, or should the duration of our ongoing clinical trials be longer than anticipated due to difficulties in patient recruitment or otherwise, our cash resources will be further strained. We may be forced to obtain additional capital before reaching clinical milestones, when our stock price or trading volume or both are low, or when the general market for biopharmaceutical, medical device, or other life sciences companies is weak. Raising capital under any of these or similar scenarios, if we can raise any at all, may lead to significant dilution to our existing stockholders. If we cannot raise additional capital when required or on acceptable terms, we will not be able to advance our product candidates or add additional product candidates to our portfolio, we may relinquish rights under our license agreements with third parties relating to our product candidates, and we will have to delay, scale back or eliminate some or all of our development programs or cease operations. See also "—We depend highly on our license agreements for our clinical stage product candidates and the loss or impairment of our rights under any license would have a materially adverse effect on our business prospects, operations and viability" below.

We intend to seek collaborations with partners to develop and commercialize our product candidates and, if we enter into such collaborations, we may not have control over several key elements relating to the development and commercialization of our product candidates.

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize our product candidates. To date, we have not entered into any such collaborations, and we may not be able to enter into any collaborations on acceptable terms, if at all. We face significant competition in seeking these types of partners. Collaborations are complex and time-consuming arrangements to negotiate and document.

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

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- changes its business strategy and areas of focus;
- determines that the market opportunity is not attractive;
- cannot obtain sufficient quantities of our products or product candidates at a reasonable cost; or
- elects to terminate our strategic collaboration for any reason.

Our success in entering into a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms of the proposed collaboration and the proposed collaborator's evaluation of several factors. Those factors may include the design and outcomes of the clinical studies, the likelihood of approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such products to customers, the potential of competing products, the strength of the intellectual property and industry and market conditions generally. The collaborator may also consider alternative products or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our products or product candidates.

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

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

If we elect to fund development or commercialization activities on our own, we will need to obtain significant additional capital, which may not be available to us when needed on acceptable terms or at all.

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

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

Today, there are a variety of hormonal and non-hormonal contraceptive options available to women, including oral contraceptive pills and intrauterine devices, newer hormonal contraceptive products including implants, injectables, vaginal rings, patches, and hormonal intrauterine systems, and non-hormonal methods such as female condoms, novel diaphragms, and new methods of female sterilization. In surveys, women have said that the features they consider most important when selecting a contraceptive method are efficacy, ease-of-use and side effects. To have significant revenue potential as a new contraceptive product option, we seek for Ovaprene to have a typical use efficacy outcome (which is the expected rate of pregnancy protection once the product is used widely under every day

circumstances) consistent with the diaphragm, which is approximately 88% effective. Clinical testing will also need to demonstrate that the device can be safely worn for multiple weeks. Should Ovaprene fail to generate the safety and efficacy data expected, our business prospects would be materially damaged.

Today's available options for treating FSAD consist primarily of over-the-counter products for vaginal lubrication. Although no products have been approved by the FDA specifically for the treatment of FSAD, we believe new product candidates will likely be developed by others. Sexual arousal can be influenced by many emotional and physiological factors and hence, our clinical trials must anticipate such factors in order to produce efficacious outcomes. Sildenafil Cream, 3.6%, is designed to increase local blood flow to the genital tissue. Even if we are successful in increasing blood flow, the product may not lead to an increase in arousal or an improvement in the overall sexual experience in some women. If we fail to generate compelling clinical results from our trials, many women suffering from sexual arousal disorder may opt not to try Sildenafil Cream, 3.6%. If we fail to produce strong clinical outcomes, our ability to build a commercial market for Sildenafil Cream, 3.6% will be materially adversely impacted.

There are several FDA-approved products in oral and vaginal forms currently available for treating bacterial vaginosis, or BV, and, if approved, DARE-BV1 will compete with those products. Current therapies for the treatment of BV primarily consist of oral and vaginal formulations of antibiotics delivered as a single dose or through multiple doses over consecutive days. Two of the most common antibiotics used today are generic clindamycin and metronidazole. In clinical studies, DARE-BV1 will need to demonstrate that it is both safe and effective in order to complete with existing and future products approved for the treatment of BV. In particular, DARE-BV1 will likely be compared with Clindesse® (clindamycin phosphate) Vaginal Cream, 2% as this treatment is a vaginally administered, single dose cream formulation of clindamycin. If we fail to generate compelling clinical outcomes, including clinical cure rates and continued clinical response rates following a single dose of DARE-BV1 that are better than existing products, physicians may opt to continue to prescribe currently available treatments rather than recommend or prescribe our product to their patients. In addition, women may prefer orally delivered options to our vaginally delivered product unless our product demonstrates significantly superior efficacy and/or safety.

See also "—The patents and the patent applications covering Sildenafil Cream, 3.6% and DARE-BV1 are limited to specific topical formulations, processes and uses of sildenafil and clindamycin, and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors," below.

Treatments to address the vasomotor symptoms associated with menopause, including hot flashes, include combinations of prescription hormones, some of which are FDA-approved and others which are prepared in compounding pharmacies. Numerous products already exist, and this number is likely to expand with time. In addition, there has been an emerging preference among some women and providers for bio-identical hormones that are chemically identical to those the body produces. DARE-HRT1 will be designed to offer a convenient vaginal ring that continuously delivers a combination of bio-identical estradiol and progesterone over 28 days. Until recently, no FDA-approved bio-identical hormone treatments existed. In 2018, Bijuva® estradiol and progesterone capsules, which are to be taken daily, received the first such approval. Studies have failed to demonstrate that bio-identical hormones are safer than other hormones, so DARE-BV1 will need to compete with many types of hormone replacement options in terms of convenience, safety and efficacy in managing vasomotor symptoms.

Today, a variety of options are available for the delivery of hormones to assist in the maintenance of pregnancy or to treat the symptoms of menopause. If approved, our intravaginal ring, or IVR, candidates will compete with pills, patches and other hormonal delivery methods, and competing with those products may prove difficult given the current marketplace and established clinical practices. We believe our clinical trials for these candidates must demonstrate efficacy comparable to or better than existing products and also prove that the candidates would be more convenient. Some women may be uncomfortable with using an IVR and may never try our IVR products. If we fail to generate compelling clinical results from clinical trials, we may lack the data to generate a commercially viable product, which would harm our business.

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

fail to generate compelling clinical results or if patients and physicians fail to appreciate the value of a therapy that is not based on estrogen, we may not have a commercially viable product, which would harm our business.

We have a relatively small number of employees to manage and operate our business.

As of March 29, 2019, we had 14 employees; nine full-time and five part-time. Our focus on limiting cash utilization requires us to manage and operate our business in a highly efficient manner, relying on external consultants for needed clinical development expertise and to limit full-time personnel resources. No assurance can be given that we will be able to run our operations or accomplish all of the objectives we otherwise would seek to accomplish with the limited personnel resources we currently have.

If we fail to attract and retain management and other key personnel, we may not successfully commercialize our product candidates, develop any product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceutical, biotechnology and medical device industries depends upon our ability to attract and retain highly qualified managerial and key personnel. We depend highly on our senior management. Losing the services of any of our senior management employees could impede, delay or prevent the development and commercialization of our product candidates, hurt our ability to raise additional funds and negatively impact our ability to implement our business plan. If we lose the services of any of our senior management employees, we might not find suitable replacements on a timely basis or at all, and our business could be materially harmed. We do not maintain “key man” insurance policies on the lives of any of our senior management employees.

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

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

We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense. During the year ending December 31, 2018, we entered into license agreements with each of SST and Juniper and a collaboration and option agreement with Orbis Biosciences Inc.; completed the acquisition of Pear Tree Pharmaceuticals, Inc. and the acquisition of assets from Hydra Biosciences, Inc.; and entered into assignment and license agreements with Hammock Pharmaceuticals, Inc., Trilogic Pharma, LLC and MilanaPharm LLC. All of these transactions could subject us to several risks, including, but not limited to:

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

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

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

We may become exposed to the risk of employees, independent contractors, principal investigators, consultants, suppliers, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could include intentional failures such as failures to: (1) comply with FDA or other regulators’ requirements, (2) provide accurate information to such regulators, (3) comply with manufacturing standards established by us and/or required by law, or (4)

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

We expect to continue to incur increased costs as a result of operating as a public company, and our management will have to devote substantial time to compliance initiatives and corporate governance practices.

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

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

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data, all of which are vital to our operations and business strategy. There can be no assurance we will succeed in preventing cyber-attacks or successfully mitigating their effects.

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

position may be adversely affected, and the further development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

Risks Related to Clinical Development, Manufacturing and Commercialization

Our success will depend heavily on our ability to develop DARE-BV1, Ovaprene, Sildenafil Cream, 3.6% and DARE-HRT1. Failure to develop these product candidates would likely adversely affect our business.

Our business depends on the successful clinical development and regulatory approval of our four clinical trial stage product candidates, which may never occur. All of our product candidates will require substantial clinical testing to demonstrate that they are safe and effective. For example, we will need to demonstrate that DARE-BV1 is a safe and effective vaginal gel option for women with BV, that Ovaprene is a safe and effective non-hormonal contraceptive option, that Sildenafil Cream, 3.6% is a safe and effective option for women seeking treatment of FSAD and that DARE-HRT1 is a convenient to use IVR that provides safe and effective relief from vasomotor symptoms associated with menopause. We have never received a regulatory approval for any product. Even if we can conduct and complete clinical trials for these product candidates, we may not obtain regulatory approval for any of them, which would have a material adverse effect on our business and operations.

We depend highly on our license agreements for our clinical stage product candidates and the loss or impairment of our rights under any license would have a materially adverse effect on our business prospects, operations and viability.

Our current portfolio includes four clinical stage product candidates, all of which we have licensed from other parties and all of which are critical to our business.

In July 2017, we entered into a license agreement with ADVA-Tec for the exclusive worldwide rights to develop and commercialize Ovaprene. In addition to standard termination rights, ADVA-Tec may terminate the license agreement if we (1) fail to make significant scheduled investments in product development activities over the course of the agreement, (2) fail to commercialize Ovaprene within 6 months of obtaining a PMA from the FDA, (3) with respect to the license in any particular country, fail to commercialize Ovaprene in that particular country within 3 years of the first commercial sale, (4) develop or commercialize a non-hormonal ring-based vaginal contraceptive device other than Ovaprene or (5) fail to conduct certain clinical trials. See “ITEM 1. BUSINESS-Overview-License Agreements-ADVA-Tec License Agreement,” above.

In February 2018, we entered into a world-wide license and collaboration agreement with SST for the exclusive worldwide rights to develop and commercialize Sildenafil Cream, 3.6% for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of the female sexual arousal disorder FSAD. The SST license agreement provides that each party will have customary rights to terminate the agreement in the event of material uncured breach by the other party and under certain other circumstances. The SST license agreement provides SST with the right to terminate it with respect to the applicable SST licensed products in specified countries upon 30 days’ notice if we fail to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan contained in the SST license agreement and do not cure such failure within 60 days of receipt of SST’s notice thereof. See “ITEM 1. BUSINESS-Overview-License Agreements-SST License and Collaboration Agreement,” above.

In April 2018, we entered into the Juniper License Agreement under which we acquired exclusive global rights to Juniper’s IVR technology platform, including the product candidates we now call DARE-HRT1, DARE-FRT1 and DARE-OAB1. Under the Juniper License Agreement, we must use commercially reasonable efforts to develop and make at least one product or process available to the public, which efforts include achieving specific diligence requirements by specific dates specified in the Juniper License Agreement, and Juniper may terminate the agreement upon 60 days’ notice for any uncured material breach by us of any of our other obligations under the agreement. See “ITEM 1. BUSINESS-Overview-License Agreements-Juniper Pharmaceuticals License Agreement,” above.

In December 2018, we entered into definitive agreements with Hammock Pharmaceuticals, Inc., TriLogic Pharma LLC and MilanaPharm LLC under which we acquired exclusive global rights to DARE-BV1 for the treatment of BV, as well as the rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological application in humans. Under the license agreement with TriLogic Pharma and MilanaPharm, we must use commercially reasonable efforts and resources consistent with those we undertake in pursuing development and commercialization of other pharmaceutical products, taking into account program-specific factors, (a) to develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany, Italy or Spain, and (b) following the first commercial sale of a licensed product or process in any jurisdiction, to continue to commercialize that product or process in that jurisdiction. MilanaPharm may terminate our license if, after having launched such product or process in such country, we, or our affiliates or

sublicensees, as applicable, discontinue the sale of, or commercially reasonable marketing efforts to sell, such product or process in such country, and fail to resume such efforts or to reasonably demonstrate a strategic justification for the discontinuation and failure. See “ITEM 1. BUSINESS-Overview-License Agreements-Hammock/MilanaPharm Assignment and License Agreement,” above.

If any of our license agreements with ADVA-Tec, SST, Juniper Pharmaceuticals, or Hammock Pharmaceuticals/MilanaPharm are terminated, impaired, or limited, we could lose the ability to develop and commercialize Ovaprene, Sildenafil Cream, 3.6%, DARE-BV1, or any of our IVR product candidates, including DARE-HRT1, as applicable, any of which would have a materially adverse effect on our business prospects and operations.

We may seek to license the product and technology rights to additional product candidates in women’s health, but there can be no assurance we will be able to do so on favorable terms or at all. There are risks, uncertainties and costs associated with identifying, licensing and advancing product candidates through successful clinical development. Even if we obtained the rights to additional product candidates, there can be no assurance these candidates will ever be advanced successfully through clinical development.

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

In May 2018, we commenced a PCT clinical trial to assess the safety and preliminary efficacy of Ovaprene, which trial is ongoing. During the second half of 2019, we intend to commence the at-home portion of the Phase 2b clinical program for Sildenafil Cream, 3.6% for FSAD and a Phase 3 clinical trial of DARE-BV1 for BV, and to initiate a Phase 1 clinical trial for DARE-HRT1. The timing of when we initiate these clinical studies will be influenced by ongoing and planned discussions with the FDA and, with respect to the Phase 2b program for Sildenafil Cream, 3.6%, the outcome of our content validity study assessing the patient reported outcome instrument proposed to be used in the Phase 2b clinical trial. DARE-HRT1 has been tested only in pre-clinical studies, and we will need to obtain authorizations from the FDA and institutional review boards of universities and clinics, as appropriate, to commence clinical testing of this candidate in humans in the United States. The initiation, conduct and completion of these and other clinical trials for our product candidates may vary dramatically due to factors within and outside of our control, and the results from early clinical trials may not necessarily be predictive of results obtained in later clinical trials. Even if results from early clinical trials are positive, we may not be able to confirm those results in future clinical trials. Further, clinical trials may never demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates. Any change in, or termination of, clinical trials could materially harm our business, financial condition, and results of operations.

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

- obtaining required funding;
- expected rates of recruitment and enrollment;
- obtaining guidance or authorizations from the FDA or foreign regulatory authorities;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining sufficient quantities of clinical trial materials for product candidates;
- obtaining IRB approval to conduct a clinical trial at a prospective site; and
- recruiting participants in a timely manner.

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

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

- participants experiencing severe side effects or other adverse events related to the investigational treatment; or
- lack of adequate funding to continue the clinical trial.

DARE-BV1 is a new vaginal formulation of clindamycin being developed for a bacterial infection known for being difficult to treat and cure. Encouraging results from a proof-of-concept study may fail to be replicated.

DARE-BV1 is a novel hydrogel formulation of clindamycin, a popular antibiotic currently available in other formulations for treating BV. BV effects over 20 million women and is known for being a difficult vaginal infection to cure. Our belief is that allowing the drug to remain in place for multiple days and requiring no intervention by the patient beyond the initial application will improve outcomes. However, other pharmaceutical companies have employed a similar approach, with clindamycin and other antibiotics, and have generated only marginally improved outcomes. To date DARE-BV1 has been studied in only 30 women in an investigator-sponsored study. We cannot predict whether our formulation will produce a successful therapeutic outcome and meet the endpoints required for regulatory approval. Even if DARE-BV1 receives approval, it will face significant competition from existing and potentially new therapies. Failure to generate compelling outcome data will hurt our ability to partner the asset and significantly decrease the asset's value.

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

Ovaprene is composed of both device and drug components and is considered a combination product by the FDA. It is a contraceptive intravaginal ring that releases locally acting spermiostatic agents and has a permeable mesh in its center designed to create a partial barrier to sperm. The barrier seeks to block the progression of sperm into the cervical mucus while the agents seek to create an environment inhospitable to sperm. Ovaprene previously underwent a request for designation, or RFD, process with the FDA that determined that the product had a device-primary mode of action and CDRH would lead the review of a PMA for the product. If the designation were to be changed to drug-primary mode of action and assigned to CDER, or if either division were to institute additional requirements for the approval of Ovaprene, we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would require us to raise additional funds and would cause us to miss anticipated timelines. Because Ovaprene is one of our lead product candidates currently in development, the impact of either a change in the lead FDA review center or the imposition of additional requirements for approval would be significant to us and would have a material adverse effect on the prospects for developing Ovaprene, our business and our financial condition.

The factors contributing to Female Sexual Dysfunction, including genital arousal disorders, are complex making the design and implementation of a successful clinical trial of Sildenafil Cream, 3.6% challenging.

Female Sexual Dysfunction disorders in women vary in nature and may be the result of a variety of physiological and psychological factors. Given the variability of factors contributing to the underlying condition, clinical studies to evaluate effectiveness in any subset of the condition under the umbrella of Sexual Dysfunction, such as female sexual arousal disorder, or FSAD, are complex. Sildenafil Cream, 3.6% is designed to work primarily by increasing blood flow to the genital tissue. Therefore, it will be critical for us to identify and enroll patients in our clinical trials of Sildenafil Cream, 3.6% for whom inadequate blood flow to the genital tissue is the primary contributor to their arousal disorder. If we fail to screen properly, and instead enroll patients with different contributing factors, the results of our clinical trials are unlikely to demonstrate effectiveness of Sildenafil Cream, 3.6%. Even if we can identify women for whom inadequate blood flow to the genital tissue is the primary contributing factor to their sexual arousal difficulties, there is no guaranty that the use of Sildenafil Cream, 3.6% will improve their general feelings of arousal or that we can utilize a patient reported outcome measure that adequately captures their genital arousal response. Given the factors contributing to arousal disorders, we may be forced to run clinical trials in large patient populations, extending the timelines and increasing the cost of product development.

Today, there are no FDA-approved treatments for FSAD, and we lack a precedent program to assist in the design of our clinical trials. These factors increase our development risk and the chance of failure. Our failure to design and implement a successful clinical trial for Sildenafil Cream, 3.6% would have materially adverse effect on our business and our financial condition.

DARE-HRT1 utilizes a vaginal ring technology never tested in women; even if it successfully advances through clinical testing, it will likely face significant commercial competition.

DARE-HRT1 represents the earliest of our clinical-stage assets and the upcoming Phase 1 study in Australia represents the first human testing of this novel intravaginal ring technology. To date, all studies have been

invitro studies or animal studies. The risks associated with earlier stage technologies tend to be higher and the rate of failure tends to be greater. While the IVR technology has generated promising results in pre-clinical studies, there can be no assurance these results will be replicated when tested in human subjects. Even if successful, many approved therapies exist for treating the vasomotor symptoms associated with menopause, including hot flashes. There is no guaranty that women will prefer the convenience of a monthly vaginal ring over pills, patches and creams. Failure of DARE-HRT1 could have a meaningful effect on the likelihood of the IVR technology being applied to another indication. These developments would materially impact the value of this technology platform to our stockholders.

Our business depends on obtaining FDA approval for our product candidates in a timely manner, and the requirements for obtaining approval may change over time, requiring more financial resources and development time than we currently anticipate.

Our success depends on our ability to obtain FDA regulatory approvals for our product candidates in a timely and cost-efficient manner. We may experience delays in our efforts to obtain such approvals for any of our product candidates, and there can be no assurance that such approvals will not be delayed, or that the FDA will ultimately approve these product candidates. The development path of our product candidates will reflect current FDA requirements, additional future FDA requirements, and may be influenced by the outcomes of other similar product candidates under development. In addition, the announcement of new requirements by the FDA, the failure of a competitive product to receive regulatory approval, or the receipt of a CRL from the FDA by another company pursuing the FDA's 505(b)(2) pathway that may have implications for our proposed pathway could impact how investors and potential strategic parties view the development risks associated with our product candidates. Changing clinical requirements for us or for others deemed to be comparable to us may adversely impact our financial resources, our development timelines and may harm the perception held by others of our business.

Successful challenges to the FDA's interpretation of Section 505(b)(2) could impact the clinical development of DARE-BV1, Sildenafil Cream, 3.6%, DARE-HRT1, DARE-VVA1, other IVR product candidates and future candidates we may license or acquire and materially harm our business.

We intend to develop and seek approval for DARE-BV1, Sildenafil Cream, 3.6%, our IVR product candidates, including DARE-HRT1, DARE-VVA1 and other candidates we may license or acquire, including ORB-204 and ORB-214, pursuant to the FDA's 505(b)(2) pathway. If the FDA determines that we may not use that pathway for the development of any of these candidates, then we would have to seek regulatory approval via a "full" or "stand-alone" NDA under Section 505(b)(1). This would require us to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval including possibly pre-clinical data. If this were to occur, the time and financial resources required to obtain FDA approval for these candidates, and the complications and risks associated with the respective product candidate or candidates, would likely substantially increase and would have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. As described above, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies and information that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development programs for DARE-BV1, Sildenafil Cream, 3.6%, our IVR product candidates, including DARE-HRT1, DARE-VVA1, ORB-204 and ORB-214.

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

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

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

Even if we receive regulatory approvals for our product candidates, they may not gain acceptance among physicians, consumers or the medical community, thereby limiting our potential to generate revenue, which will undermine our growth prospects.

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

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

If our products fail to provide a benefit over then currently available options, we are unlikely to generate sufficient revenues to achieve profitability.

The commercial success of DARE-BV1 will depend on the availability of alternative products for BV and women's preferences, in addition to the market's acceptance of our vaginal gel therapy.

Today, there are many approved products for BV, and most are generic. Should DARE-BV1 receive marketing approval, its commercial success will depend on many factors:

- strength of the efficacy data supporting the cure and clinical cure rates;
- patient satisfaction and willingness to use it again and refer it to others;
- commercial launch efforts of Lupin for Solosec®, a recently approved single-dose oral therapy;
- preference by women for a vaginally administered therapy;
- price pressure given today's high level of generic treatments; and
- approval of new entrants, including alternative, non-antibiotic treatment options.

Any of these factors could reduce the commercial potential for DARE-BV1 and place pressure on our business, financial condition, results of operation and prospects.

The commercial success of Ovaprene will depend on the availability of alternative contraceptive products and women's preferences, in addition to the market's acceptance of our non-hormonal vaginal ring.

If we receive regulatory approval to market Ovaprene, its commercial success, or the success of any other future contraceptive product candidate we may seek to develop, including our current pre-clinical candidates, will depend upon the contraceptive market and market acceptance of an alternative method. Risks related to market acceptance include:

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

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

The commercial success of Sildenafil Cream, 3.6% will depend on the availability of alternative products for Female Sexual Disorders and women's preferences, in addition to the market's acceptance of our topical cream.

Today, there are no FDA-approved products to treat FSAD. While our goal is for Sildenafil Cream, 3.6% to be the first product to receive such approval, other competitive products may obtain an approval before us. Even if we achieve that goal, the costs associated with introducing a new product into the women's health market would likely be significant, and regardless of the amount spent, there is no guarantee that our new product will be broadly adopted. Our commercial success with Sildenafil Cream, 3.6% will depend, in large part, on our ability to educate doctors and women about the need to diagnose and treat FSAD and to demonstrate the merits of Sildenafil Cream, 3.6%;

Women may be hesitant to use Sildenafil Cream, 3.6% for many reasons, including the lack of experience with any product designed to treat FSAD, the lack or perceived lack of clinical evidence supporting its benefits, and the out-of-pocket cost of Sildenafil Cream, 3.6%, particularly if it is not covered by insurance.

The commercial success of DARE-HRT1 will depend on the availability of alternative products for managing the vasomotor symptoms of menopause and women's preferences, in addition to the market's acceptance of our IVR.

Risks related to market acceptance of DARE-HRT1, if approved for hormone replacement therapy, include:

- preference for a vaginal ring delivery of hormone replacement therapy over pills, patches and creams by menopausal women;
- data regarding symptom relief of DARE-HRT1 over other hormonal treatments for vasomotor symptoms associated with menopause;
- preference for bio-identical hormones by women and health care providers; positive or negative news and research regarding bio-identicals;
- commercial launch efforts of TherapeuticsMD for Bijuva®, the first FDA-approved bio-identical product;
- new information supportive or against the use of hormones in menopause; and
- availability of insurance reimbursement for DARE-HRT1.

Depending upon the direction of the factors above, a commercial market for DARE-HRT1 may develop more slowly than expected, or not at all, and our business, financial condition, results of operation and prospects would be hurt.

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

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

Our clinical product candidates have only been tested in a small number of women over short periods of use and no data exists regarding a potential increase in fetal abnormalities in pregnant women.

If DARE-BV1, Ovaprene, or Sildenafil Cream, 3.6% are successful in their clinical development, we expect that women of child-bearing age will use them, and potentially for many months or years. To date, human clinical studies of these product candidates have been for relatively short periods of time and these product candidates lack safety data over longer periods of use. For example, while we believe the risk of adverse fetal development from using these product candidates is low, the impact of Ovaprene on fetal development has not been studied and there are no adequate or well-controlled studies of Sildenafil Cream, 3.6% in pregnant women. Thus, the risk of adverse fetal development from any one or more of these product candidates may be greater than expected. Should any of these product candidates be shown to increase the risk of adverse fetal development, our ability to develop those or other product candidates would be substantially impaired, our business prospects and operations would be materially harmed, and we could also be subject to potential claims and lawsuits.

Our Sildenafil Cream, 3.6% product candidate may pose a greater risk to older or elderly women.

FSAD is a condition that impacts women of many ages, including older and elderly populations. Sildenafil, the active ingredient in Sildenafil Cream, 3.6%, has not been tested over long periods of time in older or elderly women. Older or elderly women may react differently and adversely to Sildenafil Cream, 3.6% and we have not yet thoroughly studied the topical or clinical pharmacology of this drug candidate in different patient populations. Should Sildenafil

Cream, 3.6% show increased risk of adverse reactions, or signs thereof, in older or elderly women, our business prospects could be harmed.

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

The medical device, biotechnology and pharmaceutical industries are intensely competitive. Significant competition exists among contraceptive products, therapies to treat BV and products for managing the vasomotor symptoms associated with menopause. We anticipate new products will be developed and introduced by others in the future. Existing products have name recognition, are marketed by companies with established commercial infrastructures and with greater financial, technical and personnel resources than us. To compete and gain market share, any new product will need to demonstrate advantages in efficacy, convenience, tolerability or safety. In addition, new products developed by others could emerge as competitors to our product candidates and offer advantages and benefits over our product candidates. If we cannot compete effectively against our competitors, our business will not grow, and our financial condition and operations will suffer.

Our potential competitors include large, well-established pharmaceutical companies and specialty pharmaceutical companies, many of which have a robust product portfolio and strong franchises in women's health. These companies include Merck & Co., Inc., AMAG, Inc., TherapeuticsMD, Inc., Cooper Surgical, Inc., Agile Therapeutics, Inc., Allergan, Inc., Bayer AG, Johnson & Johnson, and Pfizer Inc. Additionally, several generic manufacturers currently market and continue to introduce new contraceptive and other products in women's health including Sandoz International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., Mylan, Inc., Perrigo Company, PLC and Amneal. Pharmaceuticals LLC. Other product candidates in development, if approved, could compete with our products.

Any of our current or future product candidates for which we pursue clinical development, may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product to be taken off the market, require it to include safety warnings or otherwise limit our sales.

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

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

Any of these events could prevent us from achieving or maintaining market acceptance of current or future product candidates, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from product sales.

The women's health market includes many generic products and the growth in generics is expected to continue, making the introduction of a branded product for contraception, BV and hormone replacement therapy difficult and expensive.

The proportion of the U.S. market made up of generic products has been increasing. In 2017, approximately 86% of the prescription volume consisted of unbranded generic products (source: IQVIA, Global Generic and Biosimilars Trends and Insights, February 13, 2018). If this trend continues, it may be more difficult for us to introduce a new branded product, if approved, at a price that will maximize our revenue and profits. Generic competition is particularly strong in the areas of contraception and the treatment of bacterial vaginosis. In order for Ovaprene and DARE-BV-1 to develop commercial markets, they must demonstrate better patient compliance and a clinical benefit in their trials in order for insurers to cover these higher cost products.

There may be additional marketing and educational efforts required to introduce a new product in order to overcome the trend towards generics and to gain access to reimbursement by payors. If we cannot introduce a product, if approved, at our desired price, if we cannot gain reimbursement from payors for an approved product, or if patients opt for a lower cost generic product and are unwilling to pay out-of-pocket or a co-pay, our revenues will be limited.

Changes in health care laws and regulations may eliminate current requirements that health insurance plans cover and reimburse FDA-cleared or approved contraceptive products without cost sharing, which could reduce demand for branded products such as Ovaprene and lead to a preference for generic options. If the out-of-pocket costs for Ovaprene are deemed by women to be high, a commercial market may never develop.

If approved, we cannot be certain that third-party reimbursement will be available for Ovaprene, and even if reimbursement is available, the amount of any such reimbursement. The ACA and subsequent regulations enacted by the Department of Health and Human Services, or DHHS, require health plans to provide coverage for women's preventive care, including all forms of FDA-cleared or approved contraception, without imposing any cost sharing on the plan beneficiary. These regulations ensure that women who wish to use an approved form of contraception may request it from their doctors and their health insurance plan must cover all costs associated with such products. These regulations may be modified, repealed, or otherwise invalidated, in whole or in part. For example, certain members of the U.S. Federal Government have attempted and are continuing to attempt to repeal the ACA and corresponding regulations, which would likely eliminate the requirement for health plans to cover women's preventive care without cost sharing. Even if the ACA is not repealed, the DHHS regulations to specifically enforce the preventive health coverage mandate could be repealed or modified under the Trump Administration, which in 2017 altered the mandate to allow certain employers and insurers to opt out of birth control coverage for religious or moral reasons. We cannot predict the timing or impact of any future rulemaking, court decisions or other changes in the law. Any repeal or elimination of the preventive care coverage rules would mean that women seeking to use prescribed forms of contraceptives may have to pay some portion of the cost for such products out-of-pocket, which could deter some women from using prescription contraceptive products, such as Ovaprene, at all. As a result, we expect that our success will depend on the willingness of patients to pay out-of-pocket for Ovaprene in the event that either they do not have insurance or their insurance requires payment of a portion of Ovaprene by the patient, thus increasing the patient's overall cost to use Ovaprene. This could reduce market demand for Ovaprene or any other contraceptive candidates we may seek to develop, such as ORB 204, ORB 214 and DARE-RH1, if and when they receive FDA approval, which would have a material adverse effect on our business, financial condition, and prospects.

As no FDA-approved treatments for FSAD currently exist, there is no precedent to help assess whether health insurance plans will cover Sildenafil Cream, 3.6%.

We cannot be certain that third-party reimbursement will be available for Sildenafil Cream, 3.6%. Even if reimbursement becomes available, the amount of such reimbursement may not make our product affordable to women and profitable to us. Insurers may deem Sildenafil Cream, 3.6% to be a life-style drug and decide not to provide reimbursement. Today, many health insurance plans provide reimbursement for male sexual arousal medications. However, we cannot predict whether they will continue to do so or whether they will do so for female sexual arousal treatments as well. In addition, the safety and efficacy data from our clinical trials may impact whether Sildenafil Cream, 3.6% will become eligible for insurance coverage, and if it does, the level of such reimbursement. In an environment of rapidly rising health care costs, insurers have been looking for ways to reduce costs, which could make it difficult for new therapies to gain coverage if they are not deemed critical or essential to gain coverage. If Sildenafil Cream, 3.6% fails to obtain insurance coverage, or if the patient's share of the cost is deemed to be expensive, a market may never develop for Sildenafil Cream, 3.6%, which would have a material adverse effect on our financial condition and prospects.

Even if we obtain regulatory approval in the United States or elsewhere to market any of our products, the reimbursement environment at the time of approval may hurt our financial prospects.

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

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

The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act.

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

- the federal health care programs' anti-kickback law (and comparable state laws), which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare, Medicaid and Veterans Health programs;
- federal and state false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from Medicare, Medicaid, Veterans Affairs, or other third-party payers;
- HIPAA (and similar state laws), which mandates, among other things, the adoption of standards to enhance the efficiency and simplify the administration of the health care system, as well as to protect the confidentiality of protected health information and electronic protected health information;
- The ACA's reporting requirements for pharmaceutical, biologic and device manufacturers regarding payments or other transfers of value made to physicians and teaching hospitals, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year; and
- the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. Regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws will involve substantial costs. Any investigation of us or the third parties with whom we contract, regardless of the outcome, would be costly and time consuming.

Our success relies on third-party suppliers and manufacturers of our product candidates, including multiple single source suppliers and manufacturers.

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

Under the terms of the SST license agreement, SST will be responsible for obtaining supplies of Sildenafil Cream, 3.6% for the Phase 2 clinical trials expected to be conducted in the United States. Thereafter, we will be responsible for obtaining pre-clinical, clinical and commercial supplies of Sildenafil Cream, 3.6%. Under the terms of the license arrangements for our other clinical-stage candidates; DARE-BV1 and DARE-HRT1, we will be responsible for sourcing the supply of the active ingredients and arranging for the manufacture of the hydrogel and IVRs. The supply of all of our product candidates, including Ovaprene and Sildenafil Cream, 3.6%, will rely on third party sources and suppliers.

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

If we were to experience an unexpected loss of supply, or if any supplier or manufacturer were unable to meet its demand for our product candidates, we could experience delays in research, planned clinical trials or commercialization. We might not find alternative suppliers or manufacturers with FDA approval, of acceptable quantity, in the appropriate volumes and at an acceptable cost. The long transition periods necessary to switch manufacturers and suppliers would significantly delay our timelines, which would materially adversely affect our business, financial conditions, results of operations and prospects.

Third-party suppliers, manufacturers, distributors or regulatory service providers may not perform as agreed or may terminate their agreements with us. Any significant problem that our suppliers, manufacturers, distributors or regulatory service providers experience could delay or interrupt our supply of materials or product candidates until the supplier, manufacturer, distributor or regulatory service provider cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available. Failure to obtain the needed quantities of our products would have a material and adverse effect on our business, financial condition, results from operations and prospects.

We have no internal sales, marketing or distribution capabilities and our model is to partner with companies with existing sales franchises to sell and distribute our products, if approved. Any failure by such third parties could negatively impact our business and our ability to develop and market any approved products.

We currently do not intend to directly sell or distribute our products into the market and instead intend to enter into agreements with third parties to sell and distribute our products. This reliance on third parties will subject us to uncertainties related to these services including the quality of such services. Further, we would depend on these distributors and partners to ensure that the distribution process accords with relevant regulations, which includes, among other things, compliance with current good documentation practices, the maintenance of records and documentation, and compliance with applicable state laws that govern the licensure of distributors of prescription medical products. Failure to comply with these requirements could result in significant remedial action, including improvement of facilities, suspension of distribution or recall of product. Furthermore, we may be unable to replace any such partner or distributor with an alternate party on a commercially reasonable or timely basis, or at all.

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

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

Our business model relies on the outsourcing of certain functions, tests and services to CROs, medical institutions and other specialist providers. We rely on these third parties to run all aspects of our clinical trials and related programs, and for quality assurance, clinical monitoring, clinical data management and regulatory expertise related to these clinical development programs. For example, we engaged a CRO to run all aspects of the PCT clinical trial for Ovaprene, and we intend to engage one or more CROs for all future clinical trial requirements needed to file for regulatory approvals. We expect to rely on third parties and CROs to perform similar functions for Sildenafil Cream, 3.6%, DARE-BV1, DARE-HRT1 and any future product candidates. There is no assurance that such organizations or individuals will

be able to provide the functions, tests or services as agreed upon, including the agreed upon price and timeline, or to our requisite quality. We will rely on the efforts of these organizations and individuals and if they fail to perform as expected, we could suffer significant delays in the development of one or more of our product candidates.

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

The commercial success of our current product candidates and any future product candidates will significantly depend on the label claims that the FDA or other regulatory authorities approve for the product.

The commercial success of any of our product candidates will significantly depend upon our ability to obtain approval from the FDA or other regulatory authorities of product labeling containing adequate information regarding a product candidate's expected features or benefits. Failure to achieve such approval will prevent or substantially limit our ability to advertise and promote such features and benefits in order to differentiate DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, DARE-HRT1, the other product candidates currently in our portfolio or any future product candidate from competing products. This failure would have a materially adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive approval from the FDA in the United States to market our current or any future product candidates we may seek to develop, we may fail to receive similar approval outside the United States.

To market a new product outside the United States, we must obtain separate marketing approvals in each jurisdiction and comply with numerous and varying regulatory requirements of other countries, including clinical trials, commercial sales, pricing, manufacturing, distribution and safety requirements. The time required to obtain approval in other countries might differ from, and be longer than, that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the United States, as well as other risks. Further, we may not obtain rights to the necessary clinical data in other countries and may have to develop our own. In addition, in many countries outside the United States, a new product must receive pricing and reimbursement approval prior to commercialization. This can result in substantial delays in these countries. Additionally, the product labeling requirements outside the United States may be different and inconsistent with the United States labeling requirements, negatively affecting our ability to market our products in countries outside the United States.

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

DARE-FRT1, DARE-OAB1, DARE-VVA1, DARE-RH1, ORB-204 and ORB-214 are in pre-clinical stages of development.

Pre-clinical studies refer to a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected. Because of their early nature, pre-clinical product candidates tend to carry a higher risk of failure as compared with clinical-stage assets. Pre-clinical candidates must generate sufficient safety and efficacy data through in vitro studies, animal studies and a variety of tests before they can be considered appropriate for testing in humans. The development risks, timeline and cost of pre-clinical assets can be high because of the unknowns and absence of data. It can be difficult to identify relevant tests and animal models for pre-clinical studies. Even if the results from our pre-clinical studies are favorable, we still may not be able to advance the candidates into clinical trials. If pre-clinical studies of product candidates do not generate strong data, DARE-FRT1, DARE-OAB1, DARE-VVA1, DARE-RH1, ORB-204 and ORB-214 may never progress to clinical development and may prove to be worthless.

Our business may be adversely affected by unfavorable macroeconomic conditions.

Various macroeconomic factors could adversely affect our business, our results of operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty) and the current and future conditions in the global financial markets.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payers and distributors to purchase, pay for and effectively distribute our products, if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future third-party manufacturers, sole source or single source suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply our clinical trial material and products, if and when approved. Failure by any of them to remain in business could have a material adverse effect on our ability to develop and obtain regulatory approvals for DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, DARE-HRT1, or any of our other current or any future product candidates, and, if approved, to provide sufficient quantities of our products to meet market demand.

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability, and the ability of our licensors, to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technologies and products. The patents and patent applications relied upon by us are licensed to us by third parties. Our ability, or the ability of our licensors, to protect our product candidates from unauthorized use or infringement by third parties depends substantially on our abilities and the abilities of such licensors to obtain and maintain, or license, valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability, and that of our licensors, to obtain or enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications. We or our licensors may not have been the first to file patent applications for these inventions.

We cannot be certain if any of the patents that cover our product candidates will be eligible to be listed in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book"). The advantage of being listed in the Orange Book is that, under Hatch-Waxman, any future generic applicant for any of our approved products needs to include a patent certification in their generic application with respect to each patent listed in the Orange Book for an approved product (referred to as the "listed drug") for which they are seeking approval. If the generic applicant believes that any of the patents in the Orange Book on the listed drug is invalid, unenforceable, or not infringed by their product, the generic applicant usually will file a "Paragraph IV" certification on that patent if they plan to challenge the patent. When a generic applicant files a Paragraph IV certification, they must provide the listed drug application (and the patent owner if different) a notice that they filed a generic application with the Paragraph IV certification. If, in reply to that notice, the listed drug holder files a patent lawsuit against the generic applicant within 45 days of the Paragraph IV notice, a 30-month automatic stay is imposed by Hatch-Waxman on FDA during which FDA may not approve the generic application (unless the patent litigation is resolved in the generic applicant's favor). These 30-month stays are major protection available in Hatch-Waxman for innovative drug makers. However, if our products are approved, but one or more of our patents are not listed in the Orange Book, generic firms that might seek approval of a generic version of our product would not have to "certify" in their generic drug applications as to any such unlisted patent. This could result in the absence of a 30-month stay and thus faster approval of some generic applications for our products.

Other companies or individuals may independently develop similar or alternative technologies or duplicate our technologies.

The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Our patent strategy for protecting DARE-BV1 includes in-licensing a patent family from TriLogic Pharma and MilanaPharm whose last claim expires in the fourth quarter of 2028 in the United States and Europe, with additional patent applications pending that could have terms into 2036. MilanaPharm has the first right to prepare, file, prosecute and maintain all such patents, at MilanaPharm's sole cost and expense. MilanaPharm and TriLogic must keep us informed regarding the preparation, filing, prosecution, and maintenance of the licensed patents, provide us with reasonable opportunity to review and comment on material communications to and from the applicable patent authorities and take all reasonable comments made by, and otherwise act in accordance with instructions provided by, us on matters related to prosecution, maintenance and enforcement related to the licensed patents. If MilanaPharm decides not to prepare, file, prosecute, or maintain any licensed patent, we have the option, in our sole discretion, to assume the control and

direction of the preparation, filing, prosecution, and maintenance of such patent at our expense, and we may deduct some or all of such patent expenses from amounts payable to MilanaPharm under our license agreement.

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

Our patent strategy for protecting Sildenafil Cream, 3.6% includes in-licensing a patent family from SST, whose last U.S. claim expires in June 2029, but which could be eligible for three-year market exclusivity under the Hatch-Waxman Act in the United States. However, if granted 3-year exclusivity, generic applicants can still submit an abbreviated application during the 3-year period and FDA is required to review the application, but will defer any approval until the end of the 3-year period. Three-year exclusivity differs from 5-year exclusivity under Hatch-Waxman, which bars the submission of a generic application during the 5-year period, with the exception that a generic application can be filed after 4 years if it contains a Paragraph IV certification challenging an Orange Book-listed patent for the brand drug.

With respect to patents related to Sildenafil Cream, 3.6%, SST has the sole right, but not the obligation, to prepare, file, prosecute and maintain such patents. We will be responsible for the costs incurred to maintain and prosecute all such patents and we will be kept informed of all strategies. However, we will have little if any, influence or control over implementing the patent strategy.

With respect to patent rights related to our IVR product candidates, including DARE-HRT1, The General Hospital Corporation (known as MGH) has the sole right to prosecute and maintain its patent rights, and we have the right to prosecute and maintain Juniper's patent rights. We will be responsible for the costs incurred by MGH to maintain and prosecute such patents and we will be kept informed of all strategies. However, we will have little, if any, influence or control over MGH's implementation of the patent strategy.

With respect to patents related to DARE-VVA1, we have the right and obligation, at our expense, to prosecute and maintain the in-licensed patent rights in certain major markets, if possible.

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

In addition, many other organizations are engaged in research and product development efforts that may overlap with our products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods we are developing or considering for development. These rights may prevent us from commercializing technology, or they may require us to obtain a license from the organizations to use the technology. We may not obtain any such licenses that may be required on reasonable financial terms, if at all, and there can be no assurance that the patents underlying any such licenses will be valid or enforceable. As with other companies in the pharmaceutical industry, we are subject to the risks that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our intellectual property rights if such activities were conducted in the United States and enforcing our intellectual property rights against such persons may be difficult or not possible.

Our patents and other intellectual property also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the United States or foreign jurisdictions, our business prospects could be substantially harmed.

In addition, because of funding limitations and our limited cash resources, we may not be able to devote the resources that we might otherwise desire to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already-issued patents.

The patents and the patent applications covering Sildenafil Cream, 3.6% and DARE-BV1 are limited to specific formulations, processes and uses of sildenafil and clindamycin, and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors.

The active ingredient in our product candidate for FSAD, Sildenafil Cream, 3.6%, is sildenafil and the active ingredient in our product candidate for the treatment of BV, DARE-BV1, is clindamycin. Patent protection for these ingredients has expired and generic products are available. As a result, a competitor that obtains the requisite regulatory approvals could offer products with the same active ingredient in a different formulation so long as the competitor does not infringe any process, use or formulation patents that we have developed, or that may not be barred by any three-year Waxman-Hatch exclusivity we might enjoy upon approval of our products.

Competitors may seek to develop and market competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for Sildenafil Cream, 3.6% and DARE-BV1 could be significantly harmed if competitors are able to develop and commercialize alternative formulations using these ingredients.

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

The active ingredients in our IVR product candidates include bio-identical progesterone, estrogen and oxybutynin, and none of those ingredients are proprietary to us. As a result, we must compete with currently available products and any future products developed by competitors using same active ingredients in a different formulation or via a different delivery system. The commercial opportunity for our IVR product candidates, including DARE-HRT1 for hormone replacement therapy, could be significantly harmed if competitors develop and commercialize alternative formulations or better delivery approaches.

The patents and the patent applications covering the use and delivery of DARE-VVA1 and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other formulations, delivery technology and systems that may be developed by competitors.

The active ingredient in DARE-VVA1, tamoxifen, is not proprietary to us. As a result, we must compete with currently available products and any future products developed by competitors using the same active ingredient in a different formulation or via a different delivery system. The commercial opportunity for our product candidate for the treatment of vulvar and vaginal atrophy could be significantly harmed if competitors develop and commercialize alternative formulations or better delivery approaches.

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

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

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

With respect to DARE-BV1, we have the initial right to enforce patents we license from TriLogic and MilanaPharm against third parties whose activities infringe such patents in a manner that could affect our exercise of the licenses granted to us, and TriLogic and MilanaPharm must reasonably cooperate with in any such suit, including, if necessary, by being joined as a party to any such suit. In some cases, MilanaPharm may assume the defense of a claim initiated by a third-party alleging infringement of a third party's intellectual property rights as a result of the manufacture or sale of a product we develop under our license agreement with TriLogic/MilanaPharm. While our license agreement would require MilanaPharm to indemnify us for certain losses arising from these third-party claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and sell DARE-BV1.

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

With respect to Sildenafil Cream, 3.6%, we have the initial right to enforce the applicable licensed patents against infringers in the field of use where a third party is exploiting a topically applied pharmaceutical product that contains at least one of the same active pharmaceutical ingredients as a licensed product, and SST will provide us with reasonable assistance (excluding financial assistance), at our expense. We also have the initial right to defend any claim initiated by any third-party alleging that a licensed product developed or commercialized under the SST license agreement has infringed any third party intellectual property rights. While the SST license agreement requires SST to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Sildenafil Cream, 3.6%.

With respect to our IVR product candidates, including DARE-HRT1, we have the first right to enforce the applicable licensed patents against third party infringers in the fields of pharmaceutical, therapeutic, preventative, diagnostic and palliative uses.

With respect to DARE-VVA1, we have the first right to enforce the applicable licensed patents against third party infringers in all fields.

Our exclusive, in-license agreements covering the critical patents and related intellectual property related to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, our IVR product candidates, including DARE-HRT1, and other product candidates we may acquire or license impose significant monetary obligations and other requirements that may adversely affect our ability to execute our business plan. The termination of any of these in-license agreements could prevent us from developing and commercializing our drug candidates and may harm our business.

Our license agreements with Hammock/MilanaPharm, ADVA-Tec, Strategic Science and Juniper Pharmaceuticals include intellectual property rights to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, and our IVR product candidates, including DARE-HRT1, respectively. These agreements, as well as our merger agreement with Pear Tree, require us, as a condition to the maintenance of our license and other rights, and as merger consideration in the case of the agreement with Pear Tree, to make milestone and royalty payments and satisfy certain performance obligations. Our obligations under these in-license agreements impose significant financial and logistical burdens upon our ability to carry out our business plan. Furthermore, if we do not meet such obligations in a timely manner, and, in the case of milestone payment requirements, if we were unable to obtain an extension of the deadlines for meeting such payment requirements, we could lose the rights to these proprietary technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Further, there is no assurance that the existing license agreements covering the rights related to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6%, and the IVR product candidates, or license agreements we enter into or acquire the rights to in the future, will not be terminated due to a material breach of the underlying agreements.

With regard to the agreement covering Ovaprene, this would include a failure on our part to make milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities, or the loss of rights to the underlying intellectual property by any such licensors. With regard to the agreement covering Sildenafil Cream, 3.6%, this would include a failure to assume responsibility for suspended development activities within the requisite period, our failure to use commercially reasonable efforts in performing development activities, or the failure on our part to make milestone and royalty payments.

With regards to the agreement covering DARE-BV1, this would include failure to use commercially reasonable efforts and resources to develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany,

Italy or Spain, our failure to make milestone and royalty payments, or our failure to continue, or to resume, using commercially reasonable marketing efforts to sell a licensed product or process in a country after having launched such product or process in that country. With regard to the agreement covering our IVR product candidates, this would include a failure on our part to make milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities or the loss of rights to the underlying intellectual property by any such licensors. With regard to the merger agreement with Pear Tree, this would include our failure to use commercially reasonable efforts to bring a product to market.

Moreover, because some of our rights to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6% and the IVR product candidates are sublicensed pursuant to underlying agreements, there is no assurance that the existing license agreements covering the rights related to DARE-BV1, Ovaprene, Sildenafil Cream, 3.6% , and DARE-HRT1 will not be terminated due to termination of the underlying agreements, or due to the loss of rights to the underlying intellectual property by Hammock's, ADVA-Tec's, SST's or Juniper Pharmaceutical's licensors. There is no assurance that we will be able to renew or renegotiate license agreements on acceptable terms if our license agreements with Hammock, ADVA-Tec, SST, TriLogic/MilanaPharm or Juniper Pharmaceuticals, or the underlying agreements are terminated. We cannot guarantee that any license agreement will be enforceable. The termination of these license agreements or our inability to enforce our rights under these license agreements would materially and adversely affect our ability to develop and commercialize DARE-BV1, Ovaprene, Sildenafil Cream, 3.6% and our IVR product candidates, including DARE-HRT1.

We may also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, we or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not have adequate remedies in respect of that disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, foreign courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

Risks Related to Our Securities

The price of our common stock may be volatile and could subject us to securities litigation, including class-action lawsuits.

The stock market in general, and the market for biopharmaceutical companies in particular, have experienced volatility that has often been unrelated to the operating performance of particular companies. The stocks of small cap and microcap companies in the biotechnology sector like ours tend to be highly volatile. We expect that the price of our common stock will be highly volatile for the next several years as we undertake studies and trials to obtain regulatory approval for our product candidates. The market price for our common stock may be influenced by many factors, including:

- failure or discontinuation of any of our research programs;
- actual or anticipated results from, and any delays in commencement or completion of, any clinical trials, as well as results of regulatory reviews relating to the approval of any product candidates;
- the level of expenses related to development of our current and future product candidates, and in particular our clinical development programs;
- commencement or termination of any collaboration or licensing arrangement;
- the results of our efforts to discover, develop, acquire or in-license product candidates or products, if any;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;

- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of health care payment systems;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- the other factors described in this “Risk Factors” section.

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

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

Our common stock is listed on the Nasdaq Capital Market. To maintain our listing we are required to satisfy continued listing requirements. For example, on November 30, 2018, we received a letter from the Listing Qualifications Department (the “Nasdaq Staff”) of the Nasdaq Stock Market (“Nasdaq”) notifying us that we were not in compliance with the minimum bid price requirement in Nasdaq Listing Rule 5550(a)(2) because the closing bid price for our common stock was less than $1.00 for the last 30 consecutive business days. On April 1, 2019, we received a letter from the Nasdaq Staff notifying us that we regained compliance with the minimum bid price requirement in Nasdaq Listing Rule 5550(a)(2) because the closing bid price of our common stock was $1.00 per share or greater for the 10 consecutive business day period from March 18, 2019 to March 29, 2019 and that the matter is now closed.

There can be no assurance we will continue satisfying the Nasdaq continued listing requirements, which include that the closing bid price of our common stock be at least $1 per share, that we have at least 300 public holders and at least 500,000 publicly held shares, that the market value of our publicly held shares be at least $1 million, and that we meet one of these standards: stockholders' equity of at least $2.5 million; market value of listed securities of at least $35 million; or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years. The delisting of our common stock for whatever reason could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management’s time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the delisting of our common stock for whatever reason may materially impair our stockholders’ ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

Pre-clinical product candidates may not be valued by investors and may be difficult to fund.

Given their early stage of development and the lack of data, many pre-clinical assets are often perceived as having low valuations by investors and pharmaceutical companies. Our investment of time and resources in such assets may not be appreciated or valued. As a result, it may be difficult for us to fund such programs. If our IVR product candidates, DARE-VVA1, DARE-RH1 or the injectable etonogestrel product candidates we may license from Orbis fail to be valued, our stock price may be adversely affected.

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

As of March 29, 2019, our executive officers and directors and their affiliates beneficially owned approximately 20% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they could exert a significant degree of influence over matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could have significant influence on

the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets, including a transaction on terms that other stockholders may desire.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time, either by us or our stockholders. For example, we sold an aggregate of 375,000 shares of our common stock in at-the-market offerings that closed in January and February 2018, and we sold 5.0 million shares of our common stock and warrants to purchase up to 3.72 million shares of our common stock in an underwritten public offering that closed in February 2018. These sales, or the perception in the market that we or holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

As of December 31, 2018, there were 1,635,790 shares of our common stock subject to outstanding options, of which 1,625,641 have been registered under the Securities Act on Form S-8. The shares so registered can be freely sold in the public market after being issued to the option holder upon exercise, except to the extent they are held by an affiliate of ours, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Furthermore, as of December 31, 2018, there were 3.75 million shares of our common stock subject to outstanding warrants to purchase common stock. To the extent these warrants are exercised, the shares underlying these warrants may be immediately sold in the public market.

The sale of our common stock through our ATM sales agreement may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline.

In January 2018, we entered into a common stock sales agreement with H.C. Wainwright & Co., LLC, in connection with an “at the market” offering, under which, from time to time, we may offer and sell up to an aggregate of $10.0 million of shares of our common stock. We call that sales agreement our “ATM sales agreement.” As of December 31, 2018, up to $8.9 million remained available for us to sell under the ATM sales agreement. Although we have the right to control whether we sell any shares, if at all, under the ATM sales agreement, and the timing and amount of sales of our shares thereunder, we are subject to certain restrictions, including, without limitation, our inability to sell, during any 12-month period, securities having an aggregate market value of not more than one-third of our public float, pursuant to General Instruction I.B.6 to Form S-3. Accordingly, we may not be able to sell shares of our common stock under the ATM sales agreement when we desire. However, to the extent we do sell shares of our common stock under the ATM sales agreement, such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline.

The exercise of our outstanding options and warrants may result in significant dilution to our stockholders.

As of December 31, 2018, we had outstanding options to purchase up to 1.64 million shares of our common stock and warrants to purchase up to 3.75 million shares of our common stock. The exercise of a significant portion of our outstanding options and/or warrants may result in significant dilution to our stockholders.

The warrants we issued in February 2018 contain anti-dilution provisions that could prevent us from obtaining additional financing.

The warrants to purchase up to 3.72 million shares of our common stock we issued and sold in the underwritten public offering that closed in February 2018 (the “February 2018 Warrants”) include price-based anti-dilution provisions. As of March 29, 2019, the exercise price of the February 2018 Warrants was $3.00 per share and the closing price of our common stock on that date was $1.40. Under the terms of the February 2018 warrants, subject to certain limited exceptions, their exercise price will be reduced each time we issue or sell (or are deemed to issue or sell) any securities, including under the ATM sales agreement, for a consideration per share less than a price equal to the exercise price of the February 2018 Warrants in effect immediately prior to such issuance or sale (or deemed issuance or sale). If we issue shares of our common stock for cash, the consideration received therefor will be deemed to be the net amount of consideration we received therefor. In addition, if we issue, sell or enter into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of our common stock, the holders of the February 2018 Warrants will have the right to substitute such variable price for the exercise price of the February 2018 Warrants then in effect.

The overhang represented by the February 2018 warrants, coupled with the anti-dilution provisions of such warrants, may make it more difficult for us to raise additional capital, because of the possible substantial dilution to any new purchaser of our securities and the ability of holders of the warrants to enter into short sales of our stock. Any potential new purchaser of our securities may choose to value our common stock in such a manner that takes into account the number of shares of our common stock that would be outstanding immediately following the exercise of all the February 2018 Warrants.

We may issue preferred stock with terms that could dilute the voting power or reduce the value of our common stock.

Our certificate of incorporation authorizes us to issue, without stockholder approval, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common stock respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our Board of Directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of our common stock.

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

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

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

In addition, even when we are no longer an emerging growth company, for so long as our public float is less than $250 million, or our annual revenues are less than $100 million and our public float is less than $700 million, we may rely on the scaled disclosure requirements available to smaller reporting companies, which permit us to include less extensive disclosure than required of other reporting companies, particularly regarding executive compensation, and to provide audited financial statements for two fiscal years, in contrast to other reporting companies, which must provide audited financial statements for three fiscal years.

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

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

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease office space for our headquarters in San Diego, California. We believe that our office space, which is in good operating condition, is suitable to meet our current needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversions of management resources and other factors. As of the date of filing this report, there is no material pending legal proceeding to which we are a party or to which any of our property is subject, and management is not aware of any contemplated proceeding by any governmental authority against the Company.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Since July 20, 2017, our common stock has traded on the Nasdaq Capital Market under the symbol “DARE.” Prior to July 20, 2017, our common stock was traded on the Nasdaq Capital Market under the symbol “CERU.”

Holders of Common Stock

As of March 29, 2019, we had approximately 44 stockholders of record.

The number of stockholders of record is based upon the actual number of holders registered on our books at such date and does not include holders of shares in "street names" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and the notes thereto included in Part II, Item 8 of this report. This following discussion includes forward-looking statements. See “PART 1—CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS,” above. Forward-looking statements are not guarantees of future performance and our actual results may differ materially from those currently anticipated and from historical results depending upon a variety of factors, including, but not limited to, those discussed in Part I, Item 1A of this report under the heading “Risk Factors,” which are incorporated herein by reference.

Business Overview

We are a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women’s health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. Our business strategy is to license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, and to take those candidates through advanced stages of clinical development. We and our wholly owned subsidiaries Private Daré, Daré Bioscience Australia Pty LTD, and Pear Tree Pharmaceuticals, Inc. operate in one business segment.

Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical stage candidates addressing unmet needs in women's health. Our portfolio includes these four clinical-stage product candidates:

- DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% for bacterial vaginosis, or BV;
- Ovaprene®, a non-hormonal monthly contraceptive intravaginal ring;

- Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil for female sexual arousal disorder, or FSAD; and
- DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy, or HRT, following menopause.

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

- DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel;
- ORB-204 and ORB-214, 6-month and 12-month formulations of injectable etonogestrel for contraception;
- DARE-FRT1, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an IVF treatment plan;
- DARE-OAB1, an intravaginal ring containing oxybutynin for the treatment of overactive bladder; and
- DARE-VVA1, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone-receptor positive breast cancer.

We expect that the bulk of our development expenses over the next two years will support the advancement of our four clinical-stage product candidates. In addition, we intend to fund a portion of the development expenses of our pre-clinical stage product candidates, particularly those like DARE-FRT1 and DARE-VVA1 that have the opportunity to advance into clinical studies more quickly. We expect that DARE-FRT1 will advance into a clinical study in approximately 12 to 18 months. Any additional product candidates we may obtain in the future will also require cash to fund their development.

DARE-BV1

DARE-BV1 is a proprietary solution-to-gel formulation containing clindamycin, an antibiotic used to treat certain bacterial infections, including BV. DARE-BV1 is designed to be administered in a convenient, single vaginal dose with a dual release pattern to prolong the duration of exposure to clindamycin at the site of infection and to potentially improve the rate of effectiveness compared to existing FDA-approved therapies. Current FDA-approved therapies for BV have clinical cure rates of less than 70 percent. In an investigator initiated pilot study that enrolled 30 women, DARE-BV1 demonstrated an 88 percent clinical cure rate in evaluable subjects (n=26) at the test-of-cure visit (Day 7-14) after one administration. We plan to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-BV1 for BV in the U.S. We expect to commence a Phase 3 clinical study of DARE-BV1 in approximately 250 women in the fourth quarter of 2019 and, if the study is successful, to be in a position to file a new drug application, or NDA, with the FDA in 2020. We anticipate that the cost of the Phase 3 clinical study, including manufacturing activities, and the NDA filing thereafter to be less than $10.0 million.

Ovaprene

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

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

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

use of a diaphragm (menstrual cycle 2) and Ovaprene (menstrual cycles 3, 4 and 5). Data from the PCT clinical trial are expected to be available in the second half of 2019. If the clinical trial demonstrates that Ovaprene is effective in preventing most sperm from progressing into the cervical canal and can be safely worn over multiple weeks, we intend to prepare and file an Investigational Device Exemption, or IDE, with the FDA to commence a pivotal clinical trial to support marketing approvals of Ovaprene in the United States, Europe and other countries worldwide.

Sildenafil Cream, 3.6%

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

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

DARE-HRT1

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

Financial Overview

We incurred a loss of approximately $16.7 million for the year ended December 31, 2018. As of December 31, 2018, we had an accumulated deficit of approximately $29.0 million and cash and cash equivalents of approximately $6.8 million.

Recent Events

In December 2018 we announced that we acquired the global rights to a clinical-stage product candidate, DARE-BV1, for the treatment of BV, as well as the rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological application in humans. We acquired these global rights through agreements we entered into with Hammock Pharmaceuticals, Inc., TriLogic Pharma, LLC and MilanaPharm LLC. See "ITEM 1. BUSINESS—License Agreements—Hammock/MilanaPharm Assignment and License Agreement," above, for more information regarding these agreements.

2017 Business Combination and Related Transactions

Until July 20, 2017, our corporate name was Cerulean Pharma Inc., or Cerulean. Cerulean was incorporated in Delaware in December 2005. On July 19, 2017, Cerulean and Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, completed a transaction in which the holders of capital stock and securities

convertible into capital stock of Private Daré, which holders are collectively referred to as the Private Daré Stockholders, sold their shares of capital stock of Private Daré to Cerulean in exchange for newly issued shares of Cerulean common stock. As a result of that transaction, Private Daré became a wholly owned subsidiary of Cerulean. As of immediately following the closing of that transaction: (i) the Private Daré Stockholders owned approximately 51% of the outstanding common stock of Cerulean, and (ii) the equity holders of Cerulean immediately prior to the closing, collectively, owned approximately 49% of the outstanding common stock of Cerulean. In connection with the transaction, Cerulean changed its name from "Cerulean Pharma, Inc." to "Daré Bioscience, Inc." We refer to the transaction described above as the Cerulean/Private Daré stock purchase transaction.

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

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

Financial Operations Overview

The results of our operations discussed in this section (A) for the full year ended December 31, 2018 and for the period from July 19, 2017 to December 31, 2017 represent our operations after giving effect to the Cerulean/Private Daré stock purchase transaction, and (B) for the period from January 1, 2017 to July 18, 2017 represent the operations of Private Daré, making a comparison between periods difficult.

Revenue

To date we have not generated any revenue and do not expect to generate any revenue for the foreseeable future. In the future, we may generate revenue from product sales, license fees, milestone and research and development payments in connection with strategic partnerships, and royalties resulting from the sales of products developed under licenses of intellectual property. Any revenue generated is expected to fluctuate from quarter to quarter as a result of the timing and amounts of any such payments. Our ability to generate product revenue will depend on the successful clinical development of our product candidates, receiving regulatory approvals to market such products and the eventual successful commercialization of product candidates. If we fail to complete the development of products candidates in a timely manner, or to receive regulatory approval for such product candidates, our ability to generate future revenue and our results of operations would be materially adversely affected.

Research and Development Expenses

Research and development expenses include research and development costs for our product candidates and transaction costs related to our acquisitions. We recognize all research and development expenses as they are incurred. Research and development expenses consist primarily of:

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

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

Conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may not obtain regulatory approval for any product candidate on a timely and cost-effective basis or at all. The probability of

success of our product candidates may be affected by numerous factors, including clinical results and data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we cannot accurately determine the duration and completion costs of development projects or when and to what extent we will generate revenue from the commercialization of any of our product candidates.

General and Administrative Expense

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

Stock-Based Compensation

The compensation cost for all stock-based awards is measured at the grant date, based on the fair value of the award (determined using a Black-Scholes option pricing model), and is recognized as an expense over the requisite service period (generally the vesting period of the equity award). Determining the fair value of stock-based awards at the grant date requires significant estimates and judgments, including estimating the market price volatility of our common stock, future employee stock option exercise behavior and requisite service periods. Due to our limited history of stock option exercises we applied the simplified method prescribed by SEC Staff Accounting Bulletin 110, *Share-Based Payment: Certain Assumptions Used in Valuation Methods - Expected Term*, to estimate expected life.

The fair value of non-employee stock options or stock awards are remeasured as the awards vest, and the resulting increase or decrease in fair value, if any, is recognized as an increase or decrease to compensation expense in the period the related services are rendered. Stock options or stock awards issued to non-employees who are not directors with performance conditions are measured and recognized when the performance is complete or is expected to be met.

Refer to Note 8 to our consolidated financial statements included in this report for more information.

Goodwill

Goodwill is recorded when the consideration paid for an acquisition exceeds the fair value of the identified net tangible and intangible assets of the acquired businesses. The allocation of purchase price for acquisitions require extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered a business or a set of net assets as a portion of the purchase price can only be allocated to goodwill in a business combination. Goodwill and intangible assets deemed to have indefinite lives are not amortized but are subject to annual impairment tests. The amounts and useful lives assigned to intangible assets that have finite useful lives require the use of estimates and the exercise of judgment. These judgments can significantly affect our net operating results. Goodwill is considered to have an indefinite life and is carried at cost.

We test goodwill at least annually, as of December 31, and between annual tests if we become aware of an event or change in circumstance that would indicate the carrying value of our goodwill may be impaired. The impairment test is performed assuming that we operate in a single operating segment and reporting unit. A goodwill impairment is the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. When impaired, the carrying value of goodwill is written down to fair value. Any excess of the reporting unit goodwill carrying value over the fair value is recognized as impairment loss.

We assessed goodwill at December 31, 2017, determined there was an impairment and recognized an impairment charge of approximately $7.5 million in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2017, and reduced our goodwill carrying value from approximately $12.7 million to $5.2 million on our consolidated balance sheet as of December 31, 2017. See Note 2, "Acquisitions," of the Notes to Consolidated Financial Statements appearing in this report for a discussion of our goodwill analysis.

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

Recently Issued Accounting Standards

See Note 1, "Organization and Summary of Significant Accounting Policies," of the Notes to Consolidated Financial Statements appearing in this report for a description of significant recent accounting standards. Other accounting standards have been issued or proposed by the Financial Accounting Standards Board or other standards-setting bodies that do not require adoption until a future date and are not expected to have a material impact on our consolidated financial statements upon adoption.

Results of Operations

Comparison of the Years ended December 31, 2018 and 2017

The results of our operations discussed in this section (A) for the full year ended December 31, 2018 and for the period from July 19, 2017 to December 31, 2017 represent our operations after giving effect to the Cerulean/Private Daré stock purchase transaction, and (B) for the period from January 1, 2017 to July 18, 2017 represent the operations of Private Daré, making a comparison between periods difficult.

The following table summarizes our consolidated results of operations for the years ended December 31, 2018 and 2017, together with the changes in those items in dollars and as a percentage:

	Years Ended December 31,		Change	
	2018	2017	Dollar	%
Operating expenses:				
General and administrative	$ 4,655,837	2,704,853	1,950,984	72 %
Research and development	6,413,956	984,749	5,429,207	551 %
License expenses	625,000	—	625,000	—
Impairment of goodwill	5,187,519	7,490,886	(2,303,367)	-31 %
Loss from operations	(16,882,312)	(11,180,488)	5,701,824	51 %
Other income (expense)	143,497	(322,629)	466,126	-144 %
Net loss	$ (16,738,815)	$ (11,503,117)	$ 5,235,698	46 %

Revenues

We did not recognize any revenue for the years ended December 31, 2018 or 2017.

General and administrative

The increase of $1,950,984 in general and administrative expenses for the year ended December 31, 2018 was primarily attributable to (i) an increase in personnel costs of $840,406 reflecting adjustments to our executive officers' compensation following the Cerulean/Private Daré stock purchase transaction to a level in line with comparable biopharmaceutical public companies as well as the hiring of additional employees which resulted in higher salary, benefit and bonus expenses; (ii) an increase in legal and professional services of $543,241 related to the costs of being a public company and to the expansion of our portfolio of product candidates; (iii) an increase in insurance costs of $245,470 related to directors and officers insurance policies; and (iv) an increase in travel costs of $105,511 related to business development activities.

Research and development

The increase of $5,429,207 in research and development expenses for the year ended December 31, 2018 was primarily attributable to (i) an increase in costs related to development activities of $4,626,688 for Ovaprene and Sildenafil Cream, 3.6%, and to a lesser extent, DARE-BV1 and DARE HRT-1; (ii) increased personnel costs of $802,519 due to increased salary, benefit and bonus expenses due to staff additions; and (iii) $507,000 of transaction costs related to the acquisition of Pear Tree and the acquisition of certain assets from Hydra.

License expenses

The increase of $625,000 in license expenses for the year ended December 31, 2018 was related to the fees paid in connection with several new license agreements: $100,000 to SST, $250,000 to Juniper, and $275,000 in aggregate to Hammock and MilanaPharma. See "ITEM 1. BUSINESS—License Agreements," above, for more information regarding these agreements.

Goodwill impairment expense

We incurred an impairment loss of $5,187,519 for the year ended December 31, 2018 and $7,490,886 for the year ended December 31, 2017 due to our determination that the carrying amount of our goodwill exceeded its estimated fair value. See Note 2, “Acquisitions,” of the Notes to Consolidated Financial statements appearing in this report for a discussion of our goodwill analysis.

Other income (expense)

The decrease of $466,126 in interest expense for the year ended December 31, 2018 primarily reflects a $322,629 expense for the year ended December 31, 2017 associated with the beneficial conversion feature associated with our convertible promissory notes, all of which were exchanged for shares of stock in connection with the Cerulean/Private Daré stock purchase transaction. No comparable expense was incurred in the current year.

Liquidity and Capital Resources and Financial Condition

We prepared the accompanying consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. For the year ended December 31, 2018, we incurred a net loss of $16.7 million which included a non-cash impairment charge to goodwill of $5.2 million. For the year ended December 31, 2017, we incurred a net loss of $11.5 million which included a non-cash impairment charge to goodwill of $7.5 million. In addition, we have a history of losses from operations, we expect negative cash flows from our operations to continue for the foreseeable future, and we expect that our net losses will continue for at least the next several years as we develop our existing product candidates and seek to acquire, license or develop additional product candidates.

At December 31, 2018, our accumulated deficit was approximately $29.0 million, our cash and cash equivalents were approximately $6.8 million, and our working capital was $6.1 million. Considering our current cash resources, we believe our existing resources will be sufficient to fund planned operations into the third quarter of 2019. For the foreseeable future, our ability to continue our operations will depend upon our ability to obtain additional capital.

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

Plan of Operations and Future Funding Requirements

Our primary uses of capital are, and we expect will continue to be, staff-related expenses, the cost of clinical trials and regulatory activities related to our product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments due under license agreements upon the successful achievement of milestones of our product candidates, legal expenses, other regulatory expenses and general overhead costs.

We expect our expenses to increase in 2019 primarily in connection with the continuation of the Ovaprene PCT clinical trial and study readout by year end 2019, the initiation of a Phase 3 clinical trial of DARE-BV1, the initiation of a Phase 1 clinical study of DARE-HRT1, the continuation of Phase 2b-related activities and potential commencement of the at-home Phase 2b clinical study of Sildenafil Cream, 3.6%, and to a lesser extent, efforts to advance our pre-clinical portfolio candidates.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue, and we cannot anticipate if, and when we will generate any revenue. We have devoted significant resources to acquiring our portfolio of product candidates and to research and development activities for our product candidates. We must obtain regulatory approvals to sell any of our products in the future. We will need to generate sufficient safety and efficacy data on our product candidates for them to be

attractive assets for potential strategic partners to license or for pharmaceutical companies to acquire, and for us to generate cash and other license fees related to such product candidates.

Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying financial statements.

We will need to raise substantial additional capital to continue to fund our operations and to successfully execute our current operating plan, including the development of our current product candidates. We are currently evaluating a variety of capital raising options, including financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover our operating expenses, including the development of our product candidates and any future product candidates we may license or otherwise acquire. The amount and timing of our capital needs have been and will continue to depend highly on many factors, including the product development programs we choose to pursue and the pace and results of our clinical development efforts. If we raise capital through collaborations, strategic alliances or other similar types of arrangements, we may have to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates we would otherwise seek to develop or commercialize. There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders. In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders. If we cannot raise capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our development programs, reduce expenses file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. See “ITEM 1A. RISK FACTORS—Risks Related to Our Business—*We will need to raise additional capital to continue our operations*,” above.

Cash Flows

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

	Years Ended December 31,	
	2018	2017
Net cash used in operating activities	$ (10,268,425)	$ (2,540,128)
Net cash provided by (used in) investing activities	(518,836)	9,918,440
Net cash provided by financing activities	10,111,952	155,000
Effect of exchange rate changes on cash and cash equivalents	(78,648)	(18,080)
Net increase (decrease) in cash	$ (753,957)	$ 7,515,232

Net cash used in operating activities

Cash used in operating activities during the year ended December 31, 2018 included a net loss of $16,738,815, decreased by non-cash impairment of goodwill of $5,187,519, acquired in-process research and development expense of approximately $507,000 and non-cash stock-based compensation expense of $139,348. Components providing operating cash were a $253,169 decrease in other receivables, an increase of $151,486 in accounts payable, a decrease of $193,495 in other current assets, and a decrease of $145,223 in other non-current assets and deferred charges. A component reducing operating cash was an increase of $91,526 in prepaid expenses.

Cash used in operating activities during the year ended December 31, 2017 consisted of our net loss of $11,503,117, decreased by non-cash impairment of goodwill of $7,490,886, non-cash stock-based compensation expense of $15,832 and by non-cash interest expense of $316,805. Major components providing operating cash included a decrease of $662,059 in other receivables, an increase of $218,267 in accounts payable, and an increase of $534,831 in accrued expenses. Major components reducing operating cash included an increase of $193,495 in other current assets and an increase of $113,021 in prepaid expenses.

Net cash provided by (used in) investing activities

Cash used in investing activities during the year ended December 31, 2018 consisted of approximately $452,000 of transaction costs associated with our acquisition of Pear Tree, $55,000 of costs associated with our acquisition of certain assets from Hydra, and $11,836 related to the purchase of property and equipment.

Cash provided by investing activities during the year ended December 31, 2017 was approximately $9.9 million, consisting of cash acquired through the Cerulean/Private Daré stock purchase transaction.

Net cash provided by financing activities

Cash provided by financing activities during the year ended December 31, 2018 consisted of $10.1 million of net proceeds from an underwritten offering of our common stock and warrants to purchase shares of our common stock and from sales of our common stock in "at the market" offerings during the first quarter of 2018.

Cash provided by financing activities during the year ended December 31, 2017 was $155,000 consisting of the proceeds from the issuance of convertible promissory notes during 2017.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements required to be included in this Item 8 are set forth in a separate section of this report commencing on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS & PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

At the conclusion of the year ended December 31, 2018, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of December 31, 2018 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15(f) of the Exchange Act). Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control-

Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2018 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States.

As an emerging growth company, we are not required to provide, and this report does not include, an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item and not set forth below will be contained in the sections titled “Election of Directors,” “Section 16(a) Beneficial Ownership Reporting Compliance,” “Corporate Governance,” “Meetings and Committees of the Board,” and “Executive Officers” in our definitive proxy statement for our 2019 Annual Meeting of Stockholders (the Proxy Statement) to be filed with the SEC within 120 days after the conclusion of our fiscal year ended December 31, 2018 and is incorporated in this report by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the section titled “Executive and Director Compensation” in our Proxy Statement and is incorporated in this report by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be contained in the section titled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Proxy Statement and is incorporated in this report by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in the sections titled “Certain Relationships and Related Transactions, and Director Independence” and “Corporate Governance” in our Proxy Statement and is incorporated in this report by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in the section titled “Ratification of Appointment of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated in this report by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this annual report on Form 10-K:

(1) Financial Statements

See “Index to Consolidated Financial Statements” on page F-1.

(2) Financial Statement Schedules

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto included in this report.

(3) Exhibits

		Incorporated by Reference				
Exhibit Number	Description of Exhibit	Form	File No.	Filing Date	Exhibit No.	Filed Herewith
2.1§	Stock Purchase Agreement dated as of March 19, 2017, entered into by and among Cerulean Pharma Inc., Daré Bioscience, Inc. and equityholders of Daré Bioscience, Inc. named therein.	8-K	001-36395	3/20/2017	2.1	
2.2§ Δ	Agreement and Plan of Merger, dated as of April 30, 2018, by and among Daré Bioscience, Inc., Daré Merger Sub, Inc., Pear Tree Pharmaceuticals, Inc., and Fred Mermelstein and Stephen C. Rocamboli, as Holders' Representatives	10-Q	001-36395	8/13/2018	10.10	
3.1	Restated Certificate of Incorporation, 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	10-Q	001-36395	08/14/2017	3.1	
3.2	Second Amended and Restated By-Laws (as amended through May 28, 2018)	10-Q	001-36395	8/13/2018	3.1	
4.1	Specimen stock certificate evidencing the shares of common stock	10-K	001-36395	03/28/2018	4.1	
4.2	Warrant, dated January 8, 2015, issued to Hercules Technology Growth Capital, Inc.	8-K	001-36395	01/08/2015	4.1	
4.3	Preferred Stock Purchase Warrant to purchase shares of Series D Convertible Preferred Stock issued by the Registrant to Lighthouse Capital Partners VI, L.P., as amended	S-1	333-194442	03/10/2014	10.20	

4.4	Form of Stock Purchase Warrant of the Registrant to purchase shares of Series C Convertible Preferred Stock	S-1	333-194442	03/10/2014	10.19
4.5(a)	Form of Warrant to Purchase Shares of Common Stock (February 2018 Underwritten Offering)	8-K	001-36395	02/13/2018	4.1
4.5(b)	Form of Amendment to Warrant to Purchase Common Stock entered into as of June 27, 2018	10-Q	001-36395-181175221	11/13/2018	4.1
10.1Δ	License and Collaboration Agreement dated February 11, 2018 between Daré Bioscience, Inc., Strategic Science and Technologies-D, LLC and Strategic Science Technologies, LLC	10-K/A	001-36395	04/30/2018	10.1
10.2Δ	License Agreement dated March 19, 2017, between Daré Bioscience Operations, Inc. and ADVA-Tec, Inc.	10-Q	001-36395	11/13/2017	10.1
10.3 (a)	Common Stock Sales Agreement, dated January 4, 2018, by and between Daré Bioscience, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-36395	01/04/2018	10.1
10.3(b)	Amendment No. 1 to Common Stock Sales Agreement, dated August 24, 2018, by and between Daré Bioscience, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-36395	08/27/2018	10.2
10.4(a)*	Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	8-K	001-36395-18949535	7/12/2018	10.1
10.4(b)*	Form of Incentive Stock Option Agreement for grants under the Dare Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	10-Q	001-36395	08/13/2018	10.3
10.4(c)*	Form of Nonstatutory Stock Option Agreement for grants under the Dare Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	10-Q	001-36395	08/13/2018	10.4
10.5	Form of indemnification agreement between the registrant and each of its executive officers and directors	S-1	333-194442	03/10/2014	10.16
10.6*	Non-Employee Director Compensation Policy (as amended through April 9, 2018)	10-Q	001-36395	8/13/2018	10.2

10.7Δ	Exclusive License Agreement made as April 24, 2018 by and between Juniper Pharmaceuticals, Inc., and Daré Bioscience, Inc.	10-Q	001-36395	8/13/2018	10.1	
10.8(a)Δ	Amended and Restated Exclusive License Agreement, dated as of July 14, 2006, by and between Fred Mermelstein, Ph.D. and Janet Chollet, M.D., and Pear Tree Women's Health Care, Inc.	10-Q	001-36395	8/13/2018	10.5	
10.8(b)Δ	Amendment No. 1 to the Amended and Restated Exclusive License Agreement, dated as of October 10, 2007, by and among Fred Mermelstein, Ph.D. and Janet Chollet, M.D., and Pear Tree Pharmaceuticals, Inc.	10-Q	001-36395	8/13/2018	10.6	
10.8(c)Δ	Amendment No. 2 to the Amended and Restated Exclusive License Agreement, dated as of February 13, 2017, by and among Fred Mermelstein, Ph.D., and Janet Chollet, M.D., Pear Tree Pharmaceuticals, Inc. and Bernadette Klamerus	10-Q	001-36395	8/13/2018	10.7	
10.8(d)Δ	Exclusive License Agreement, dated as of February 13, 2017, by and between GYN Holdings, Inc., a wholly owned subsidiary of Pear Tree Pharmaceuticals, Inc. and Bernadette Klamerus	10-Q	001-36395	8/13/2018	10.8	
10.8(e)Δ	Exclusive License Agreement, dated as of September 15, 2017, by and between Fred Mermelstein, Ph.D., Janet Chollet, M.D., Pear Tree Pharmaceuticals, Inc., and Stephen C. Rocamboli	10-Q	001-36395	8/13/2018	10.9	
10.9	2014 Employee Stock Purchase Plan	S-1/A	333-194442	03/31/2014	10.26	
10.10(a)Δ	Assignment Agreement by and between Daré Bioscience, Inc. and Hammock Pharmaceuticals, Inc. effective as of December 5, 2018					X
10.10(b)Δ	First Amendment to the License Agreement effective as of December 5, 2018 by and among Daré Bioscience, Inc., TriLogic Pharma, LLC and MilanaPharm LLC					X
10.11(a)*	2007 Stock Incentive Plan	S-1	333-194442	03/10/2014	10.1	

10.11(b)	Form of Incentive Stock Option Agreement under 2007 Stock Incentive Plan	S-1	333-194442	03/10/2014	10.2	
10.11(c)*	Form of Nonstatutory Stock Option Agreement under 2007 Stock Incentive Plan	S-1	333-194442	03/10/2014	10.3	
10.11(d)	Stock Option Agreement and Contingent Consideration Award Agreement, dated March 31, 2013, between Cerulean Pharma, Inc. and Alan Crane	S-1	333-194442	03/10/2014	10.24	
10.11(e)	Amendment to the Stock Option Agreement and Termination of Contingent Consideration Award dated September 16, 2014, by and between Cerulean Pharma, Inc. and Alan Crane	10-Q	001-36395	11/13/2014	10.4	
10.12(a)*	Amended and Restated 2015 Employee, Director and Consultant Equity Incentive Plan of Daré Bioscience Operations, Inc.	10-K	001-36395	03/28/2018	10.14(a)	
10.12(b)*	Form of Stock Option Agreement under the Amended and Restated 2015 Employee, Director and Consultant Equity Incentive Plan of Daré Bioscience Operations, Inc.	10-K	001-36395	03/28/2018	10.14(b)	
10.13*	Employment Agreement by and between Daré Bioscience, Inc. and Sabrina Martucci Johnson dated as of August 15, 2017	8-K	001-36395	08/18/2017	10.1	
10.14*	Employment Agreement by and between Daré Bioscience, Inc. and Lisa Walters-Hoffert dated as of August 15, 2017	8-K	001-36395	08/18/2017	10.2	
21.1	Subsidiaries of the registrant					X
23.1	Consent of Mayer Hoffman McCann P.C.					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X

32.1#	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
32.2#	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Label Linkbase Document	X
101.PRE	XBRL Taxonomy Presentation Linkbase Document	X

§	All schedules (or similar attachments) have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The registrant will furnish copies of any schedules to the Securities and Exchange Commission upon request.
Δ	Confidential treatment has been requested or granted to certain confidential information contained in this exhibit.
*	Management contract or compensatory plan or arrangement
#	Furnished herewith. This certification is being furnished solely to accompany this report pursuant to U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated herein by reference into any filing of the registrant whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Daré Bioscience, Inc.

By: /s/ SABRINA MARTUCCI JOHNSON

President and Chief Executive Officer

Date: April 1, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ SABRINA MARTUCCI JOHNSON Sabrina Martucci Johnson	President and Chief Executive Officer (Principal Executive Officer) and Director	April 1, 2019
/s/ LISA WALTERS-HOFFERT Lisa Walters-Hoffert	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	April 1, 2019
/s/ ROGER L. HAWLEY Roger L. Hawley	Chairman of the Board and Director	April 1, 2019
/s/ JESSICA D. GROSSMAN Jessica D. Grossman	Director	April 1, 2019
/s/ SUSAN L. KELLEY Susan L. Kelley, M.D.	Director	April 1, 2019
/s/ GREGORY W. MATZ Gregory W. Matz	Director	April 1, 2019
/s/ WILLIAM H. RASTETTER William H. Rastetter, Ph.D.	Director	April 1, 2019
/s/ ROBIN STEELE Robin Steele, J.D., L.L.M.	Director	April 1, 2019

DARÉ BIOSCIENCE, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Stockholders of Daré Bioscience, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of **Daré Bioscience, Inc.** and Subsidiaries ("the Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company had recurring losses from operations, negative cash flow from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.

April 1, 2019
San Diego, California

We have served as the Company's auditor since 2017.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31,	
	2018	2017
Assets		
Current Assets		
Cash and cash equivalents	$ 6,805,889	$ 7,559,846
Other receivables	31,037	284,206
Prepaid expenses	403,097	311,571
Other current assets	—	193,495
Total current assets	7,240,023	8,349,118
Property and equipment, net	9,396	—
Goodwill	—	5,187,519
Other non-current assets	577,968	723,191
Total assets	$ 7,827,387	$ 14,259,828
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable	$ 459,705	$ 308,219
Accrued expenses	631,351	658,434
Total current liabilities	1,091,056	966,653
Deferred rent	9,711	392
Total liabilities	1,100,767	967,045
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.01 par value, 5,000,000 shares authorized		
None issued and outstanding	—	—
Common stock: $0.0001 par value, 120,000,000 shares authorized, 11,422,161 and 6,047,161 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	1,143	605
Accumulated other comprehensive loss	(96,728)	(18,080)
Additional paid-in capital	35,791,972	25,541,210
Accumulated deficit	(28,969,767)	(12,230,952)
Total stockholders' equity	6,726,620	13,292,783
Total liabilities and stockholders' equity	$ 7,827,387	$ 14,259,828

See Accompanying Notes to Consolidated Financial Statements.

The operations presented in the Consolidated Financial Statements and accompanying notes (A) for the year ended December 31, 2018, and for the year ended December 31, 2017 that include the period from July 19, 2017 to December 31, 2017, represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) for the year ended December 31, 2017 that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 2, "Acquisitions - Cerulean/Private Daré Stock Purchase Transaction," of the Notes to the Consolidated Financial Statements appearing in this report for a discussion of the Cerulean/Private Daré stock purchase transaction.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2018	2017
Operating expenses:		
General and administrative	$ 4,655,837	$ 2,704,853
Research and development expenses	6,413,956	984,749
License expenses	625,000	—
Impairment of goodwill	5,187,519	7,490,886
Total operating expenses	16,882,312	11,180,488
Loss from operations	(16,882,312)	(11,180,488)
Other income (expense)	143,497	(322,629)
Net loss	$ (16,738,815)	$ (11,503,117)
Foreign currency translation adjustments, net of tax	(78,648)	(18,080)
Comprehensive loss	$ (16,817,463)	$ (11,521,197)
Loss per common share - basic and diluted	$ (1.57)	$ (3.56)
Weighted average number of common shares outstanding:		
Basic and diluted	10,732,421	3,232,278

See Accompanying Notes to Consolidated Financial Statements.

The operations presented in the Consolidated Financial Statements and accompanying notes (A) for the year ended December 31, 2018, and for the year ended December 31, 2017 that include the period from July 19, 2017 to December 31, 2017, represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) for the year ended December 31, 2017 that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 2, “Acquisitions - Cerulean/Private Daré Stock Purchase Transaction,” of the Notes to the Consolidated Financial Statements appearing in this report for a discussion of the Cerulean/Private Daré stock purchase transaction.

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

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity (deficit)
Balance at December 31, 2016	**910,000**	**$ 91**	**$ 17,123**	**$ —**	**$ (727,835)**	**$ (710,621)**
Conversion of convertible notes into common stock	638,805	64	912,899	—	—	$ 912,963
Beneficial conversion feature	—	—	316,805	—	—	$ 316,805
Business combination upon merger	4,498,356	450	24,278,551	—	—	$ 24,279,001
Stock-based compensation	—	—	15,832	—	—	$ 15,832
Net loss	—	—	—	—	(11,503,117)	$ (11,503,117)
Foreign currency translation adjustments	—	—	—	(18,080)	—	$ (18,080)
Balance at December 31, 2017	**6,047,161**	**$ 605**	**$ 25,541,210**	**$ (18,080)**	**$ (12,230,952)**	**$ 13,292,783**
Net proceeds from issuance of common stock and warrants	375,000	38	734,197	—	—	734,235
Issuance of common stock via public offering, net	5,000,000	500	9,377,217	—	—	9,377,717
Stock-based compensation	—	—	139,348	—	—	139,348
Net loss	—	—	—	—	(16,738,815)	(16,738,815)
Foreign currency translation adjustments	—	—	—	(78,648)	—	(78,648)
Balance at December 31, 2018	**11,422,161**	**$ 1,143**	**$ 35,791,972**	**$ (96,728)**	**$ (28,969,767)**	**$ 6,726,620**

See Accompanying Notes to Consolidated Financial Statements.

The operations presented in the Consolidated Financial Statements and accompanying notes (A) for the year ended December 31, 2018, and for the year ended December 31, 2017 that include the period from July 19, 2017 to December 31, 2017, represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) for the year ended December 31, 2017 that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 2, "Acquisitions —Cerulean/Private Daré Stock Purchase Transaction," of the Notes to the Consolidated Financial Statements appearing in this report for a discussion of the Cerulean/Private Daré stock purchase transaction.

Daré Bioscience, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2018	2017
Operating activities:		
Net loss	$ (16,738,815)	$ (11,503,117)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,440	—
Stock-based compensation	139,348	15,832
Non-cash interest	—	316,805
Acquired in-process research and development	507,000	—
Impairment of goodwill	5,187,519	7,490,886
Changes in operating assets and liabilities, net impact of acquisition:		
Other receivables	253,169	662,059
Prepaid expenses	(91,526)	(113,021)
Other current assets	193,495	(193,495)
Other non-current assets and deferred charges	145,223	(2,800)
Accounts payable	151,486	218,267
Accrued expenses	(27,083)	534,831
Interest payable	—	33,233
Deferred rent	9,319	392
Net cash used in operating activities	(10,268,425)	(2,540,128)
Investing activities:		
Cash acquired through merger	—	9,918,440
Purchases of property and equipment	(11,836)	—
Acquisition of Pear Tree and Hydra assets	(507,000)	—
Net cash provided by (used in) investing activities	(518,836)	9,918,440
Financing activities:		
Net proceeds from issuance of common stock and warrants	10,111,952	—
Proceeds from issuance of convertible promissory notes	—	155,000
Net cash provided by financing activities	10,111,952	155,000
Effect of exchange rate changes on cash and cash equivalents	(78,648)	(18,080)
Net change in cash and cash equivalents	(753,957)	7,515,232
Cash and cash equivalents, beginning of year	7,559,846	44,614
Cash and cash equivalents, end of year	$ 6,805,889	$ 7,559,846
Non-cash transactions:		
Shares issued in connection of business combination and assumed equity awards	$ —	$ 24,279,001
Conversion of convertible notes into common stock	$ —	$ 912,962
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ 837

See Accompanying Notes to Consolidated Financial Statements.

The operations presented in the Consolidated Financial Statements and accompanying notes (A) for the year ended December 31, 2018, and for the year ended December 31, 2017 that include the period from July 19, 2017 to December 31, 2017, represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) for the year ended December 31, 2017 that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult. See Note 2, "Acquisitions

—Cerulean/Private Daré Stock Purchase Transaction," of the Notes to the Consolidated Financial Statements appearing in this report for a discussion of the Cerulean/Private Daré stock purchase transaction.

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and business

Daré Bioscience, Inc. is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's health. Daré Bioscience, Inc. and its wholly owned subsidiaries, Daré Bioscience Operations, Inc., Daré Bioscience Australia Pty LTD, and Pear Tree Pharmaceuticals, Inc., operate in one segment. In this report, the "Company" refers collectively to Daré Bioscience, Inc. and its wholly owned subsidiaries, unless otherwise stated or the context otherwise requires.

The Company is driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. The Company's business strategy is to license or otherwise acquire the rights to differentiated product candidates in women's health, some of which have existing clinical proof-of-concept data, and to advance those candidates through clinical development and regulatory approval alone or in collaboration with strategic partners.

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

- DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis, or BV;
- Ovaprene, a non-hormonal monthly contraceptive intravaginal ring;
- Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder, or FSAD; and
- DARE-HRT1 (formerly JNP-0201), a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause.

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

- DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel;
- ORB-204 and ORB-214, 6-month and 12-month formulations of injectable etonogestrel for contraception;
- DARE-FRT1 (formerly JNP-0301), an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an *in vitro* fertilization, or IVF, treatment plan;
- DARE-OAB1 (formerly JNP-0101), an intravaginal ring containing oxybutynin for the treatment of overactive bladder; and
- DARE-VVA1 (formerly PT-101), a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone-receptor positive breast cancer.

The Company's primary operations have consisted of, and are expected to continue to consist of, product research and development and advancing its portfolio of product candidates through clinical development and regulatory approval.

To date, the Company has not obtained any regulatory approvals for any of its product candidates, commercialized any of its product candidates or generated any product revenue. The Company is subject to several risks common to clinical-stage biopharmaceutical companies, including dependence on key individuals, competition from other companies, the need to develop commercially viable products in a timely and cost-effective manner, and the need to obtain adequate additional capital to fund the development of product candidates. The Company is also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of

products, uncertainty of market acceptance of products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, and product liability.

On July 19, 2017, the Company completed its business combination with Daré Bioscience Operations, Inc., a privately held Delaware corporation, in accordance with the terms of the Stock Purchase Agreement, dated as of March 19, 2017, See Note 2, "Acquisitions - Cerulean/Private Daré Stock Purchase Transaction." The operations presented in the Consolidated Financial Statements and accompanying notes (A) for the year ended December 31, 2018 and for the year ended December 31, 2017 that include the period from July 19, 2017 to December 31, 2017, represent the operations of the Company following the Cerulean/Private Daré stock purchase transaction, and (B) for the year ended December 31, 2017 that include the period from January 1, 2017 to July 18, 2017 represent the operations of the Company when it was private, making a comparison between periods difficult.

Basis of presentation

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or U.S. GAAP as defined by the Financial Accounting Standards Board, or FASB.

Going Concern

The Company has prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, as of December 31, 2018, the Company had an accumulated deficit of approximately $29.0 million and had cash and cash equivalents of approximately $6.8 million. The Company also had negative cash flow from operations of approximately $10.3 million for the year ended December 31, 2018. The Company has a history of losses from operations, expects negative cash flows from its operations will continue for the foreseeable future, and expects that its net losses will continue for at least the next several years as it develops its existing product candidates and seeks to acquire, license or develop additional product candidates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

During the first quarter of 2018, the Company received gross proceeds of approximately $11.3 million, resulting in net proceeds of approximately $10.1 million, from sales of its securities in registered offerings (see Note 7). During the third and fourth quarter of 2018, the Company received approximately $225,000 from a federal grant.

The Company is focused primarily on the development and commercialization of innovative products in women’s health. The Company will continue to incur significant research and development and other expenses related to these activities. If the clinical trials for any of the Company’s product candidates fail to produce successful results such that those product candidates do not advance in clinical development, then the Company’s business and prospects may suffer. Even if the product candidates advance in clinical development, they may fail to gain regulatory approval. Even if the product candidates are approved, they may fail to achieve market acceptance, and the Company may never become profitable. Even if the Company becomes profitable, it may not sustain profitability.

Based on current cash resources, the Company believes its existing resources will be sufficient to fund planned operations into the third quarter of 2019. For the foreseeable future, the Company's ability to continue its operations will depend upon its ability to obtain additional capital.

Although the Company has cash and cash equivalents of approximately $6.8 million at December 31, 2018, the Company will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current operating plan, including the development of its current product candidates. The Company is currently evaluating a variety of capital raising options, including financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements to cover its operating expenses, including the development of its product candidates and any future product candidates it may license or otherwise acquire. The amount and timing of the Company's capital needs have been and will continue to depend highly on many factors, including the product development programs the Company chooses to pursue and the pace and results of its clinical development efforts. If the Company raises capital through collaborations, strategic alliances or other similar types of arrangements, it may have to relinquish, on terms that are not favorable to the Company, rights to some of its technologies or product candidates it would otherwise seek to develop or commercialize. There can be no assurances that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders. Additionally, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will not be able to continue development

of its product candidates, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If the Company becomes unable to continue as a going concern, the Company may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its consolidated financial statements, and stockholders may lose all or part of their investment in the Company's common stock. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Principles of Consolidation

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

Grant Funding

The Company receives certain research and development funding through a grant issued by a division of the National Institutes of Health. The funding is recognized in the statement of operations as a reduction to research and development expense as the related costs are incurred to meet those obligations over the grant period. The Company adopted this policy in 2018. For the year ended December 31, 2018, the Company recognized approximately $225,000 in the statement of operations as a reduction to research and development expense.

Use of Estimates

The preparation of the consolidated 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 FDA, 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.

Cash and Cash Equivalents

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

Concentration of Credit Risk

The Company maintains cash balances at various financial institutions and such balances commonly exceed the $250,000 amount insured by the Federal Deposit Insurance Corporation. The Company also maintains money market funds at various financial institutions which are not federally insured although are invested primarily in the U.S. The Company has not experienced any losses in such accounts and management believes that the Company does not have significant risk with respect to such cash and cash equivalents.

Fair Value of Financial Instruments

U.S. GAAP defines fair value as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date, and also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available. The three-level hierarchy of valuation techniques established to measure fair value is defined as follows:

- Level 1: inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: inputs other than level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of assets or liabilities.
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Cash and cash equivalents of $6.8 million and $7.6 million measured at fair value as of December 31, 2018 and 2017, respectively, are classified within Level 1. Other receivables are financial assets with carrying values that approximate fair value due to the short-term nature of these assets. Accounts payable and accrued expenses and other liabilities are financial liabilities with carrying values that approximate fair value due to the short-term nature of these liabilities.

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

The Company records goodwill based on the fair value of the assets acquired. In determining the fair value of the assets acquired, the Company utilizes extensive accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired. The Company uses the discounted cash flow method to estimate the value of intangible assets acquired.

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 $12.7 million related to the Cerulean/Private Daré stock purchase transaction on July 19, 2017. The Company assessed goodwill at December 31, 2017 and determined there was an impairment and recognized an impairment charge of approximately $7.5 million in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2017 and reduced the carrying value of goodwill from $12.7 million to approximately $5.2 million on its consolidated balance sheet as of December 31, 2017.

The Company reassessed goodwill at March 31, 2018, determined there was an impairment and recognized an impairment charge of approximately $5.2 million in the interim consolidated statement of operations and comprehensive loss for the three months ended March 31, 2018. As of March 31, 2018, the goodwill carrying value on the Company's consolidated balance sheet was written off in its entirety. See Note 2, "Acquisitions."

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. Its chief operating decision maker is the chief executive officer. The Company has one operating segment, women's reproductive health.

Research and Development Costs

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses, manufacturing process-development and scale-up activities, fees paid to clinical and regulatory consultants, clinical trial and related clinical trial manufacturing expenses, fees paid to clinical research organizations, or CRO's, and investigative sites, transaction expenses incurred in connection with the expansion of the product portfolio through acquisitions and license and option agreements, payments to universities under the Company's license agreements and other outside expenses. Research and development costs are expensed as incurred. Nonrefundable advance payments, if any, for goods and services used in research and development are recognized as an expense as the related goods are delivered or services are performed.

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.

There were stock options exercisable into 584,670 and 539,896 shares of common stock outstanding at December 31, 2018 and 2017, respectively. These securities were not included in the computation of diluted loss per share because they are antidilutive, but they could potentially dilute earnings (loss) per share in future years.

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 Accounting Standards Codification, or 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 December 31, 2018, the Company did not record any liabilities for uncertain tax positions.

During 2018, the Company recorded a provision for income taxes of $3,200. There was no provision for income taxes recorded during 2017. Management evaluated the Company's tax positions and as of December 31, 2018 has approximately $924,000 of unrecognized benefits. The tax years 2015 to 2018 remain open to examination by federal and state taxing authorities while the statute for net operating losses generated remain open beginning in the year of utilization.

Indemnifications

As permitted under Delaware law, the Company has entered into indemnification agreements with its officers and directors that provide that the Company will indemnify the directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by such director or officer in any action or proceeding arising out of their service as a director and/or officer. The term of the indemnification is for the officer's or director's lifetime. During the year ended December 31, 2018, the Company did not experience any losses related to those indemnification obligations. The Company does not expect significant claims related to these indemnification obligations, and consequently, has concluded the fair value of the obligations is not material. Accordingly, as of December 31, 2018 and 2017, no amounts have been accrued related to such indemnification provisions.

Recent Accounting Pronouncements Not Yet Adopted

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

Recently Adopted Accounting Standards

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

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

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

In January 2017, FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment (Topic 350)*. The guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. The guidance should be adopted on a prospective basis for the annual or any

interim goodwill impairment tests beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company's adoption of this standard on September 30, 2017 did not have a material impact on the Company's consolidated financial statements.

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

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

2. ACQUISITIONS

Cerulean/Private Daré Stock Purchase Transaction

On July 19, 2017, the Company completed its business combination with Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré, in accordance with the terms of the Stock Purchase Agreement dated as of March 19, 2017, or the Daré Stock Purchase Agreement, by and among the Company Private Daré and the holders of capital stock and securities convertible into capital stock of Private Daré named therein, or the Private Daré Stockholders. Pursuant to the Daré Stock Purchase Agreement, each Private Daré Stockholder sold their shares of capital stock in Private Daré to the Company in exchange for newly issued shares of the Company's common stock, and as a result, Private Daré became a wholly owned subsidiary of the Company and the Private Daré Stockholders became majority stockholders of the Company. In connection with the closing of that transaction, the Company changed its name from "Cerulean Pharma, Inc." to "Daré Bioscience, Inc." In this report, that transaction is referred to as the Cerulean/Private Daré stock purchase transaction and "Cerulean" refers to Cerulean Pharma, Inc. before that transaction closed.

The Cerulean/Private Daré stock purchase transaction was accounted for as a reverse merger under the acquisition method of accounting whereby Private Daré was considered to have acquired Cerulean for financial reporting purposes because immediately upon completion of the transaction, Private Daré stockholders held a majority of the voting interest of the combined company. Pursuant to business combination accounting, the Company applied the acquisition method, which requires the assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The excess of the purchase price over the assets acquired and liabilities assumed represents goodwill. The goodwill is primarily attributable to the cash and cash equivalents at closing of approximately $9.9 million and the impact of the unamortized fair value of stock options granted by Cerulean that were outstanding immediately before the transaction closed of approximately $3.7 million. The unamortized fair value of such stock options relates to an option modification approved on March 19, 2017 that provided for an acceleration of vesting of such options upon a change in control event. Such modification became effective upon the closing of the Cerulean/Private Daré stock purchase transaction. Hence, the unamortized fair value of such stock options is deemed to be part of total purchase consideration and goodwill. Transaction costs associated with the Cerulean/Private Daré stock purchase transaction of $0.96 million are included in general and administrative expense. The total purchase price consideration of approximately $24.3 million represents the fair value of the shares of Cerulean stock issued in connection with the Cerulean/Private Daré stock purchase transaction and the unamortized fair value of the stock options described above, which was allocated as follows:

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

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

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

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

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

Pear Tree Merger

On April 30, 2018, the Company entered into an Agreement and Plan of Merger, the Merger Agreement, with Pear Tree Pharmaceuticals, Inc., or Pear Tree, Daré Merger Sub, Inc., a wholly-owned subsidiary of the Company, or Merger Sub, and two individuals in their respective capacities as Pear Tree stockholders' representatives. The transactions contemplated by the Merger Agreement closed on May 16, 2018, and as a result, Pear Tree became the Company's wholly owned subsidiary. The Company acquired Pear Tree to secure the rights to develop DARE-VVA1, a proprietary vaginal formulation of tamoxifen, as a potential treatment for vulvar and vaginal atrophy.

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

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

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

3. CONVERTIBLE PROMISSORY NOTES

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

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

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

The Company recognized interest expense of $0 and $316,805 as of December 31, 2018 and December 31, 2017, respectively, relating to the convertible promissory notes.

4. OTHER NON-CURRENT ASSETS

Other non-current assets consisted of the following:

	As of December 31,	
	2018	2017
Prepaid insurance, long-term portion	$ 562,266	$ 720,391
Deposits	15,702	2,800
Total other non-current assets	$ 577,968	$ 723,191

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2018	2017
Accrued compensation and benefits expenses	$ 416,234	$ 316,024
Accrued legal and professional expenses	32,457	259,600
Accrued clinical and related expenses	182,660	82,810
Total accrued expenses	$ 631,351	$ 658,434

6. INCOME TAXES

The components of loss from continuing operations before provision for income taxes consists of the following (in thousands):

	Years Ended December 31,	
	2018	2017
Domestic	$ 16,707	$ 11,503
Foreign	107	18
Loss before taxes	$ 16,814	$ 11,521

The difference between the provision for income taxes (benefit) and the amount computed by applying the U.S. federal income tax rate for the years ended December 31, 2018 and 2017 are as follows:

	Years Ended December 31,	
	2018	2017
Federal statutory rate	21.0 %	34.0 %
State income tax, net of federal benefit	2.42 %	1.3 %
Permanent differences	0.31 %	(2.8)%
Research and development credit	1.24 %	1.9 %
Stock compensation	(0.08)%	(3.4)%
Federal rate reduction under tax reform	— %	(204.7)%
Goodwill impairment	(6.48)%	(22.1)%
Change in valuation allowance	(18.43)%	195.8 %
Effective income tax rate	(0.02)%	— %

The major components of the Company's deferred tax assets as of December 31, 2018 and 2017 are shown below (in thousands).

	2018	2017
Net operating loss carryforwards	$ 40,436	$ 32,412
Research and development credit carryforwards	3,321	3,102
Capitalized research and development costs	13,334	15,176
Other amortizable costs	11	3,377
Stock compensation	1,941	1,877
Total deferred tax assets	59,043	55,944
Valuation allowance	(59,043)	(55,944)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Under applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a valuation allowance of $59.0 million and $55.9 million was established at December 31, 2018 and 2017 respectively, to offset the net deferred tax assets. When and if management determines that it is more

likely than not that the Company will be able to utilize the deferred tax assets prior to their expiration, the valuation allowance may be reduced or eliminated.

The increase in valuation allowance of approximately $3.1 million for the year ending December 31, 2018 is primarily related to an increase in net operating losses generated during the year. The increase in valuation of approximately $55.6 million for the year ending December 31, 2017 is primarily related to acquired deferred tax assets in the transaction with Cerulean Pharma Inc, offset by a reduction in deferred tax assets revalued at the reduced federal tax rate under the U.S. Tax Cuts and Jobs Act enacted in December of 2017.

The Company has U.S. federal net operating loss, or NOL, carryforwards available at December 31, 2018 of approximately $153.8 million (2017– $122.5 million) of which, $135.0 million begin expiring in 2027 unless previously utilized and $18.8 million that do not expire but are limited to 80% of taxable income in a given year. The Company has state NOL carryforwards of $119.9 million (2017 – $102.7 million) that begin expiring in 2032 unless previously utilized. The Company has U.S. federal research credit carryforwards available at December 31, 2018 of approximately $2.2 million (2017 – $2.5 million) that begin expiring in 2027 unless previously utilized. The Company has state research credit carryforwards of $1.1 million (2017 – $1.6 million) that begin expiring in 2022 unless previously utilized. The difference between federal and state NOL carryforwards is primarily due to previously expired state NOL carryforwards.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not yet completed an evaluation of ownership changes. To the extent an ownership change occurs, the NOL and credit carryforwards and other deferred tax assets may be subject to limitations.

On December 22, 2017, President Trump signed into law the “Tax Cuts and Jobs Act,” or TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and NOL carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a “worldwide” system of taxation to a territorial system.

The TCJA permanently lowers the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective for tax years including or commencing on January 1, 2018. As a result of the reduction of the corporate federal income tax rate to 21%, U.S. GAAP requires companies to revalue their deferred tax assets and deferred tax liabilities as of the date of enactment, with the resulting tax effects accounted for in the reporting period of enactment. This revaluation resulted in a provision of $23.6 million to income tax expense in continuing operations and a corresponding reduction of the Company’s valuation allowance. As a result of the offsetting valuation allowance, there is no impact to the Company’s income statement for the year ended December 31, 2018 from the reduction in federal income tax rates.

A reconciliation of the beginning and ending amount of uncertain tax benefits is as follows:

	Years Ended December 31,	
	2018	2017
Beginning uncertain tax benefits	$ 846	$ —
Current year - increases	78	65
Current year - purchase accounting increases	—	781
Ending uncertain tax benefits	$ 924	$ 846

Included in the balance of uncertain tax benefits at December 31, 2018 are $924,000 of tax benefits that, if recognized, would impact the effective tax rate. The Company anticipates that no material amounts of unrecognized tax benefits will be settled within 12 months of the reporting date.

The Company’s policy is to record estimated interest and penalties related to uncertain tax benefits as income tax expense. As of December 31, 2018 and 2017, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The tax years 2015 through 2018 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the U.S. The statute of limitations for U.S. net operating losses utilized in future years will remain open beginning in the year of utilization.

No additional provision has been made for U.S. income taxes related to undistributed foreign earnings of the Company's wholly owned Australian subsidiary or for unrecognized deferred tax liabilities for temporary differences related to investments in subsidiaries. As such, earnings are expected to be permanently reinvested, the investments are permanent in duration, or the Company has estimated that no additional tax liability will arise as a result of the distribution of such earnings. A liability could arise if amounts are distributed by the subsidiary or if the subsidiary is ultimately disposed. It is not practical to estimate the additional income taxes, if any, related to permanently reinvested earnings. There are no unremitted earnings as of December 31, 2018.

7. STOCKHOLDERS' EQUITY

ATM Sales Agreement

In January 2018, the Company entered into a common stock sales agreement under which the Company may sell up to an aggregate of $10 million in gross proceeds through the sale of shares of common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement plus certain legal expenses. The common stock sales agreement was amended in August 2018 to refer to the Company's shelf registration statement on Form S-3 (File No. 333-227019) that was filed to replace the Company's shelf registration statement on Form S-3 (File No. 333-206396) that expired on August 28, 2018.

During the year ended December 31, 2018, the Company issued and sold 375,000 shares under the common stock sales agreement for gross proceeds of approximately $1.0 million and incurred offering expenses of approximately $338,000. All such shares were sold during January and February 2018.

Underwritten Public Offering

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

Common Stock Warrants

The warrants issued in the February 2018 underwritten offering have an exercise price of $3.00 per share and are exercisable immediately and for five years from issuance. The warrants include a price-based anti-dilution provision, which provides that, subject to certain limited exceptions, the exercise price of the warrants will be adjusted downward if the Company issues or sells (or is deemed to issue or sell) securities at a price that is less than the exercise price in effect immediately prior to such issuance or sale (or deemed issuance or sale). In that case, the exercise price of the warrants will be adjusted to equal the price at which the new securities are issued or sold (or are deemed to have been issued or sold). In addition, subject to certain exceptions, if the Company issues, sells or enters into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of the Company's common stock, the warrant holders have the right to substitute such variable price for the exercise price of the warrant then in effect. The warrants are exercisable only for cash, unless a registration statement covering the shares issued upon exercise of the warrants is not effective, in which case the warrants may be exercised on a cashless basis. A registration statement covering the shares issued upon exercise of the warrants is currently effective.

The Company estimated the fair value of the warrants as of February 15, 2018 to be approximately $3.0 million which has been recorded in equity as of the grant date. The Company early adopted ASU 2017-11 and as a result has recorded the fair value of the warrants as equity (see Note 1).

No warrants were exercised during the year ended December 31, 2018 or 2017. During the year ended December 31, 2018, warrants to purchase 170 shares of the Company's common stock expired. As of December 31, 2018, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
2,906	$	120.40	December 1, 2021
3,737	$	120.40	December 6, 2021
17,190	$	60.50	January 8, 2020
6,500	$	1.00	April 4, 2026
3,720,500	$	3.00	February 15, 2023
3,750,833			

Common Stock

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

The authorized capital of the Company consists of 120,000,000 shares of common stock with a par value of $0.0001 and 5,000,000 shares of preferred stock with a par value of $0.01 per share at December 31, 2018. The issued and outstanding common stock of the Company consisted of 11,422,161 and 6,047,161 shares with a par value of $0.0001 as of December 31, 2018 and 2017, respectively. There were no shares of preferred stock outstanding as of December 31, 2018 or 2017.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2018 and 2017:

	As of December 31,	
	2018	2017
Common stock reserved for issuance upon exercise of warrants outstanding	3,750,833	30,502
Common stock reserved for issuance upon exercise of options outstanding	1,635,790	539,896
Common stock reserved for future equity awards (under the Amended 2014 Plan)	421,244	46,479
Total	5,807,867	616,877

8. STOCK-BASED COMPENSATION

The 2015 Employee, Director and Consultant Equity Incentive Plan

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

Based on the exchange ratio and after giving effect to the reverse stock split effected in connection with the closing of the Cerulean/Private Daré stock purchase transaction, such options were replaced with options to purchase 10,149 shares of the Company's common stock, all of which were outstanding as of December 31, 2018.

Private Daré issued 900,000 and 200,000 shares of fully vested restricted stock to non-employees under the 2015 Private Daré Plan during 2015 and 2016, respectively. In connection with the closing of the Cerulean/Private Daré stock purchase transaction, the Company assumed these shares and replaced them with 223,295 restricted shares

of the Company's common stock (after giving effect to the reverse stock split effected in connection with the closing of the Cerulean/Private Daré stock purchase transaction).

No further awards may be granted under the 2015 Private Daré Plan following the closing of the Cerulean/Private Daré stock purchase transaction.

2014 Employee Stock Purchase Plan

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

Amended and Restated 2014 Stock Incentive Plan

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

There are 2,046,885 shares of common stock authorized for issuance under the Amended 2014 Plan. The number of authorized shares will increase annually on the first day of each fiscal year until, and including, the fiscal year ending December 31, 2024 by the least of (i) 2,000,000, (ii) 4% of the number of outstanding shares of common stock on such date, or (iii) an amount determined by the Company's board of directors.

In March 2017, the Company's board of directors approved two modifications to outstanding stock options granted under the 2014 Plan to participants providing services to the Company as of that date. One modification extended the exercise period of such stock options to two years after such participant's termination date, unless the exercise period absent such modification would be longer. The other modification provided for accelerated vesting of such stock options upon a change in control event. These modifications resulted in unamortized fair value expense of approximately $3.7 million and was recorded as part of the total consideration in the Cerulean/Private Daré stock purchase transaction (see Note 2). The two modifications resulted in certain options remaining outstanding that would have otherwise expired.

As of December 31, 2018, 421,244 shares of common stock were reserved for future issuance under the Amended 2014 Plan, and options to purchase 1,635,790 shares of the Company's common stock granted under the Amended 2014 Plan were outstanding.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Amended 2014 Plan, and related information for the years ended December 31, 2018 and 2017. The exercise price of all options granted during the years ended December 31, 2018 and 2017 was equal to the market value of the Company's common stock on the date of grant.

As of December 31, 2018, unamortized stock-based compensation expense of $1,035,847 will be amortized over the weighted average period of 3.31 years.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	5,000	$ 0.01		
Granted	565,372	32.90		
Exercised	—	—		
Forfeited	(30,476)	54.25		
Outstanding at December 31, 2017 (1)	539,896	$ 31.40		
Granted	1,096,050	1.08		
Exercised	—	—		
Forfeited	(156)	59.48		
Outstanding at December 31, 2018 (1)	1,635,790	$ 11.08	8.77	$ 7,109
Options exercisable at December 31, 2018	584,670	$ 29.03	7.20	$ 7,109
Options vested and expected to vest at December 31, 2018	1,635,790	$ 11.08	8.77	$ 7,109

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

Compensation Expense

Total stock-based compensation expense related to stock options granted to employees and directors recognized in the consolidated statement of operations is as follows:

	Years Ended December 31,	
	2018	2017
Research and development	$ 24,929	$ —
General and administrative	114,419	15,832
Total	$ 139,348	$ 15,832

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 years ended December 31, 2018 and 2017 is as follows:

	2018	2017
Expected life in years	10	5.4
Risk-free interest rate	2.52%	1.85%
Expected volatility	121%	72%
Forfeiture rate	—	—
Dividend yield	—%	—%
Weighted-average fair value of options granted	1.03	4.46

Restricted Stock After the Cerulean/Private Daré Stock Purchase Transaction

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

9. COMMITMENTS AND CONTINGENCIES

Operating Lease

The Company entered into a facility lease agreement that commenced on July 1, 2018 for 3,169 square feet of office space for its corporate headquarters. The term of the lease is 37 months and terminates on July 31, 2021. The Company has the option to extend the term of the lease for one year. The gross monthly base rent is $8,873, which

will increase approximately 4% per year, subject to certain future adjustments. The base rent was abated during the second month of the lease. Future minimum lease payments at December 31, 2018 total $289,108. The Company recognizes rent expense by the straight-line method over the lease term. As of December 31, 2018, deferred rent totaled $9,711.

Future minimum annual lease payments under the Company's facility lease as of December 31, 2018, are as follows:

	Operating Leases
2019	$ 108,570
2020	112,943
2021	67,595
Total minimum lease payments	$ 289,108

Legal Proceedings

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 consolidated financial statements.

Risk Management

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure of 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 to 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 will fully vest and accelerate subject to the conditions outlined in such officer's employment agreement.

License and Research Agreements

ADVA-Tec License Agreement

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

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

Research and Development. ADVA-Tec will conduct certain research and development work as necessary to allow the Company to seek a Premarket Approval, or PMA, from the United States Food and Drug Administration, or the FDA, and will supply the Company with its requirements of Ovaprene for clinical and commercial use on commercially reasonable terms. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, such amounts totaling $5.0 million

in the aggregate over the first three years, to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first.

Milestone Payments. The Company will pay to ADVA-Tec: (1) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones; and (2) up to $20 million in the aggregate based on the achievement of certain worldwide net sales milestones. The development and regulatory milestones include: the completion of a successful postcoital clinical study, which is required before the Company can commence a Phase 3 pivotal human clinical trial; approval by the FDA to commence such Phase 3 pivotal human clinical trial; successful completion of such Phase 3 pivotal human clinical trial; the FDA's acceptance of a PMA filing for Ovaprene; the FDA's approval of the PMA for Ovaprene; obtaining Conformité Européenne Marking of Ovaprene in at least three designated European countries; obtaining regulatory approval in at least three designated European countries; and obtaining regulatory approval in Japan. Because these milestone payments depend upon the successful progress of the Company's product development programs, the Company cannot estimate with certainty when these payments will occur, if ever.

Royalty Payments. After the commercial launch of Ovaprene, the Company will pay to ADVA-Tec royalties based on aggregate annual net sales of Ovaprene in specified regions, at a royalty rate that will vary between 1% and 10% and will increase based on various net sales thresholds.

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

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

SST License and Collaboration Agreement

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

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

Invention Ownership. The Company retains rights to inventions made by its employees, SST retains rights to inventions made by its employees, and each party shall own a 50% undivided interest in all joint inventions.

Joint Development Committee. The parties will collaborate through a joint development committee that will determine the strategic objectives for, and generally oversee, the development efforts of both parties under the SST License Agreement.

Development. The Company must use commercially reasonable efforts to develop the Licensed Products in the Field of Use in accordance with a development plan in the SST License Agreement, and to commercialize the Licensed Products in the Field of Use. The Company is responsible for all reasonable internal and external costs and

expenses incurred by SST in its performance of the development activities it must perform under the SST License Agreement.

Royalty Payments. SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

Milestone Payments. SST will be eligible to receive payments (1) ranging from $0.5 million to $18.0 million in the aggregate on achieving certain clinical and regulatory milestones in the U.S. and worldwide, and (2) between $10.0 million to $100 million in the aggregate upon achieving certain commercial sales milestones. If the Company enters into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST.

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

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

Orbis Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement, or the Orbis Agreement, with Orbis Biosciences, or Orbis, for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). Under the Orbis agreement, the Company paid Orbis $300,000 to conduct the first stage of development work, Stage 1, as follows: $150,000 upon signing the Orbis Agreement, $75,000 at the 50% completion point, not later than 6 months following the date the Orbis Agreement was signed (which the Company paid in September 2018), and $75,000 upon delivery by Orbis of the 6-month batch, not later than 11 months following the date the Orbis Agreement was signed (which the Company paid in January 2019). Upon Orbis successfully completing Stage 1 of the development program and achieving the predetermined target milestones for Stage 1, the Company will have 90 days to instruct Orbis whether to commence the second stage of development work, Stage 2. Should the Company execute its option to proceed to Stage 2, it will have to provide additional funding to Orbis for such activities.

Pre-clinical studies for the 6- and 12-month formulations have been completed, including establishing pharmacokinetics and pharmacodynamics profiles. The collaboration with Orbis will continue to advance the program through formulation optimization with the goal of achieving sustained release over the target time period.

The Orbis Agreement provides the Company with an option to enter into a license agreement for ORB-204 and ORB-214 should development efforts be successful.

Juniper Pharmaceuticals - License Agreement

In April 2018, the Company entered into an Exclusive License Agreement, or the Juniper License Agreement, with Juniper Pharmaceuticals, Inc., or Juniper, under which Juniper granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Juniper, to make, have made, use, have used, sell, have sold, import and have imported products and processes; and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Juniper to make, have made, use, have used, sell, have sold, import and have imported products and processes. The Company is entitled to sublicense the rights granted to it under the Juniper License Agreement.

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

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

Annual Maintenance Fee. The Company will pay an annual license maintenance fee to Juniper on each anniversary of the date of the Juniper License Agreement, the amount of which will be $50,000 for the first two years and $100,000 thereafter, and which will be creditable against royalties and other payments due to Juniper in the same calendar year but may not be carried forward to any other year.

Milestone Payments. The Company must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the Juniper License Agreement.

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

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

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

Pear Tree Acquisition

The Company may be required to make certain royalty and milestone payments under the Merger Agreement (see Note 2).

Hammock/MilanaPharm Assignment and License Agreement

On December 5, 2018, the Company entered into (a) an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and (b) a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, the Company acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In DARE-BV1, this proprietary technology is formulated with clindamycin, an antibiotic used to treat certain bacterial infections, including BV, and has been engineered to produce a dual release pattern after vaginal application, providing maximum duration of exposure to clindamycin at the site of infection.

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

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

Milestone Payments. The Company will pay to MilanaPharm (1) up to $300,000 in the aggregate upon achievement of certain development milestones; and (2) up to $1.75 million in the aggregate upon achieving certain commercial sales milestones.

Foreign Sublicense Income. The Company will pay MilanaPharm a low double-digit percentage of all income received by the Company or its affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions.

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

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

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

In addition to customary termination rights for all parties, MilanaPharm may terminate the license granted to the Company solely with respect to a licensed product or process in a country if, after having launched such product or process in such country, (1) the Company, or its affiliates or sublicensees, discontinue the sale of such product or process in such country and MilanaPharm notifies the Company of such termination within 60 days of having first been notified by the Company of such discontinuation, or (2) the Company, or its affiliates or sublicensees, (A) discontinues all commercially reasonable marketing efforts to sell, and discontinues all sales of, such product or process in such country for nine months or more, (B) fails to resume such commercially reasonable marketing efforts within 120 days of having been notified of such failure by MilanaPharm, (C) fails to reasonably demonstrate a strategic justification for the discontinuation and failure to resume to MilanaPharm, and (D) MilanaPharm gives 90 days’ notice to the Company.

The following is a summary of other terms of the Assignment Agreement with Hammock:

Assignment; Technology Transfer. Hammock assigned and transferred to the Company all of its right, title and interest in and to the MilanaPharm License Agreement and agreed to cooperate to transfer to the Company all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan to be agreed upon by the parties, with a goal for the Company to independently practice the licensed intellectual property as soon as commercially practical in order to develop and commercialize the licensed products and processes.

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

Milestone Payments. The Company will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones.

Term. The Assignment Agreement will terminate upon the later of (1) completion of the parties' technology transfer plan, and (2) payment to Hammock of the last of the payments described above, including the milestone payments.

Employee Benefit – 401(k) Plan

The Company has a 401(k) retirement plan, or the 401(k) Plan, covering all qualified employees. The 401(k) Plan allows each participant to contribute a portion of their base wages up to an amount not to exceed an annual statutory maximum. The 401(k) Plan includes a Safe Harbor Plan that provides a Company match up to 4% of salary. The Company made matching contributions of $53,252 and $0 during the years ended December 31, 2018 and 2017, respectively.

10. GRANT AWARD

In April 2018, the Company received a Notice of Award for the first $224,665 of the anticipated $1.9 million in grant funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a division of the National Institutes of Health, or the NIH. The award will be applied to clinical development efforts supporting Ovaprene. The balance of the award is contingent upon, among other matters, assessment of the results of the first phase of the research and availability of funds. The Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment. As of December 31, 2018, the Company has received payments totaling $224,665. Such reimbursement payments are recognized in the statement of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

11. SUBSEQUENT EVENTS

Grant Award

On March 11, 2019, the Company announced that it received a Notice of Award for an additional $982,851 of the anticipated $1.9 million in grant funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (See Note 10). The second award followed the NIH's review of an interim data analysis and other results of the first phase of the research supporting Ovaprene. The award will be applied to clinical development efforts supporting Ovaprene. The remaining portion of the award under the grant, $730,722, is contingent upon, among other matters, assessment that the results of the ongoing Ovaprene study satisfy specified requirements set out in the award notice, and the availability of funds. The Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment.

Exhibit 10.10(a)

Execution Version

ASSIGNMENT AGREEMENT

THIS ASSIGNMENT AGREEMENT ("Agreement") is entered into by and between Daré Bioscience, Inc. ("Daré"), having a place of business at 3655 Nobel Drive, Suite 260, San Diego, California 92122, and Hammock Pharmaceuticals, Inc. ("Hammock"), having a place of business at 16700 Hammock Creek Place, Charlotte, North Carolina 28278, and is effective as of December 5, 2018 ("Effective Date").

BACKGROUND

A. Hammock, TriLogic Pharma, LLC ("TriLogic") and MilanaPharm LLC ("MilanaPharm," and together with TriLogic, the "Licensors") are parties to that certain Exclusive License Agreement dated January 9, 2017 ("MilanaPharm Agreement"), a copy of which is attached hereto as Exhibit A.

B. Daré wishes to take assignment of the MilanaPharm Agreement from Hammock, and Hammock is willing to assign the MilanaPharm Agreement to Daré, all in accordance with the terms of this Agreement and the First Amendment to License Agreement dated concurrently herewith by and among Daré, TriLogic Pharma, LLC and MilanaPharm LLC.

C. Licensors have consented to the assignment of the MilanaPharm Agreement from Hammock to Daré.

D. Capitalized terms used but not defined in this Agreement shall have the meanings ascribed to them in the MilanaPharm Agreement.

AGREEMENT

In consideration of the mutual promises, covenants, and conditions hereinafter set forth and in exchange for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. ASSIGNMENT

1.1. Assignment. Hammock hereby irrevocably assigns and transfers to Daré all of Hammock's right, title and interest in and to the MilanaPharm Agreement. Hammock and Daré shall cooperate with one another as may be reasonably necessary to implement and document the assignment of the MilanaPharm Agreement from Hammock to Daré.

1.2. No Assumed Liabilities. Daré does not assume any obligations of Hammock arising from any breach under the MilanaPharm Agreement prior to the Effective Date, for which Hammock shall be solely liable, and Hammock shall be relieved of any obligations of Daré arising from any breach under the MilanaPharm Agreement upon and after the Effective Date, for which Daré shall be solely liable. All rights and obligations under the MilanaPharm Agreement arising, accruing or

relating to the period commencing upon the Effective Date shall be allocated to, and be the obligation of, Daré.

1.3. Assumption. Daré hereby accepts and assumes the assignment of the MilanaPharm Agreement.

2. TECHNOLOGY TRANSFER

Promptly after the Effective Date, and from time to time thereafter upon Daré's written request, Hammock will cooperate in such manner as Daré may reasonably request in order to transfer to Daré during normal business hours (i) all Data, (ii) all Hammock Data; (iii) all tangible materials in Hammock's possession or control relating to or embodying Licensed Intellectual Property (including samples, prototypes and inventories); (iv) all Licensed Know-How; and (v) any and all other documentation, data, materials, samples and information including, referencing or embodying the Data, Hammock Data or Licensed Know-How in Hammock's possession or control, including without limitation all information and materials made available by MilanaPharm to Hammock in connection with the MilanaPharm Agreement (all of (i) through (v) is collectively, "**Technology and Data**"). The parties acknowledge their mutual goal is for Daré to independently practice the Licensed Intellectual Property as soon as commercially practical in order to successfully develop and commercialize Licensed Products. The parties shall use good faith and diligent efforts to agree in writing on a technology transfer plan that (a) identifies all Technology and Data, (b) describes the manner in which Hammock will transfer the Technology and Data to Daré; and (c) describes a process by which Daré may verify that it has receive all Technology and Data (the "**Technology Transfer Plan**") within ten (10) business days after the Effective Date, and the parties will carry out the Technology Transfer Plan.

3. FINANCIAL PROVISIONS

3.1. Upfront Fee. Daré will pay Hammock a single upfront fee of Two Hundred Fifty Thousand Dollars ($250,000.00) on the Effective Date.

3.2. Deferred Fee. Within fifteen (15) days of the first to occur of (a) the first (1st) anniversary of the Effective Date or (b) the closing of an equity financing with a third party by Daré in which aggregate proceeds of at least Ten Million Dollars ($10,000,000) are raised (such date, the "Deferred Payment Trigger Date"), Daré shall pay Hammock a fee of Two Hundred Fifty Thousand Dollars ($250,000) (the "Deferred Fee"). The Deferred Fee may be paid either (a) in cash or (b) if Daré is then a publicly traded company, by delivery of freely transferrable shares of common stock of Daré (the "Shares"), with such choice being made in the sole discretion of Daré. In the event that Daré elects to pay the Deferred Fee in Shares, the number of Shares shall be determined by dividing $250,000 by the volume weighted average of the sale price for Daré common stock on its primary trading exchange during the fifteen trading day period immediately preceding the Deferred Payment Trigger Date; *provided, however*, that if the number of shares issued to Hammock would require stockholder approval under Nasdaq Rule 5635 (or any successor rule), then Daré may elect to deliver to Hammock that number of shares of common stock as will not require stockholder approval and, for the remainder, within ninety (90) days after the Deferred Payment Trigger Date either (i) pay the cash value thereof based on the volume weight average sale price referred to above or (ii) obtain stockholder approval and issue such remaining shares, in each case accompanied by interest on the

cash value thereof at the rate of 8% per annum from the Deferred Payment Trigger Date throught the issue or payment date (which interest shall be payable at Daré's option in cash or, if stockholder approval is obtained, shares of common stock at the same valuation).

3.3. Clinical and Regulatory Milestones.

3.3.1. BV Indication. Daré will pay Hammock the following amounts within [***] days after achievement of the following events that occur with respect to the first Licensed Product:

[***] Dollars ($[***])	[***]
[***] Dollars ($[***])	[***]
[***] Dollars ($[***])	[***]

For clarity, each of the milestone payments in the above table shall be paid only once, regardless of the number of Licensed Products, and the maximum amount of payments payable by Daré to Hammock pursuant to the above table is [***] Dollars ($[***]).

3.3.2. Non-BV Indication. Daré will pay Hammock [***]Dollars ($[***]) within [***] days after [***]. For clarity, the foregoing milestone payment shall be paid only once, regardless of the number of Licensed Products and the number of indications.

3.4. Other Applicable Terms.

3.4.1. All amounts due to Hammock under this Agreement will be paid in U.S. dollars, by wire transfer in immediately available funds to an account designated in writing by Hammock. Any payment not delivered on time shall accrue interest from the date due until paid in full at the rate of the lower of [***]% per month or the highest rate allowed under applicable laws; *provided* that no interest shall accrue on any amounts being disputed in good faith by Daré with respect to which Daré is making diligent and good faith efforts to resolve.

3.4.2. On a quarterly basis, Daré will provide such information as Hammock may reasonably request, as to the status of the milestones referred to in Section 3.3.1 and 3.3.2, including but not limited to [***], and the progress with respect to the achievement of such milestones from the last such report to Hammock.

4. TERM

This Agreement will commence on the Effective Date and will automatically terminate upon the later of (i) completion of the Technology Transfer Plan and (ii) payment to Hammock of the last payment to which it may be entitled under Section 3. Sections 5, 6.1, 6.3, 6.4, 6.5, 6.6 and this sentence will survive termination of this Agreement.

5. CONFIDENTIALITY

5.1. Definition. "Confidential Information" means, with respect to a party hereto, non-public information that such party provides to the other party under this Agreement, including but not limited to, financial statements and projections, customer and supplier information, research,

designs, plans, methods, processes, procedures, trade secrets and know-how, whether in verbal, tangible or intangible form. Notwithstanding the foregoing, Confidential Information of a party shall not include information which the other party can establish: (a) is within the public domain prior to the time of the disclosure by the disclosing party or thereafter becomes within the public domain other than as a result of disclosure or use by the receiving party or any of its representatives in violation of this Agreement; (b) was, on or before the date of disclosure in the rightful possession of the receiving party as demonstrated by its business records kept in the ordinary course; (c) is, as demonstrated by its business records kept in the ordinary course, lawfully acquired by the receiving party from a third party having the right to disclose without burden of confidentiality to either party; or (d) is hereafter independently developed by the receiving party without use of the disclosing party's Confidential Information, as verified by the receiving party's written or electronic records.

5.2. Obligations. Each party shall (i) maintain the other party's Confidential Information in confidence during the term of this Agreement and thereafter; (ii) limit dissemination of the other party's Confidential Information to those of such party's and its Affiliates' directors, officers, employees, agents, subcontractors, and sublicensees who require such Confidential Information in order to perform this Agreement, (iii) not disclose the other party's Confidential Information to any other person or entity, and (iv) use the other party's Confidential Information only to the extent necessary to exercise its rights and perform its obligations under this Agreement. If the receiving party is compelled to disclose Confidential Information of the disclosing party by order of a court of competent jurisdiction or applicable law, any such disclosure shall not be a breach hereunder, provided that reasonable advance notice is given to the disclosing party to permit the disclosing party to ensure that such disclosure is subject to all applicable governmental or judicial protection available for like material, and the receiving party shall cooperate with the disclosing party's efforts in minimizing or opposing such disclosure at the disclosing party's request and expense.

5.3. Securities Filings. Notwithstanding Section 5.2, if either party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other Applicable Law, the party shall notify the other party of such intention and shall provide such other party with a copy of relevant portions of the proposed filing prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to the terms and conditions of this Agreement, and shall use reasonable and diligent efforts to obtain confidential treatment of the terms and conditions of this Agreement that such other party requests be kept confidential, and shall only disclose Confidential Information that is requested by the Securities and Exchange Commission or legally required to be disclosed. No such notice shall be required under this Section 5.3 if the description of or reference to this Agreement contained in the proposed filing has been included in a mutually agreeable press release or in any previous filing made by the either party hereunder or otherwise approved by the other party.

6. GENERAL PROVISIONS

6.1. Expenses. Each party will bear its own expenses incurred in connection with the negotiation, preparation and performance of this Agreement, except as (a) expressly set forth herein

or (b) $[***] of legal fees otherwise payable by Hammock to Goodwin Procter LLP, which shall be paid by Daré.

6.2. Representations and Warranties.

6.2.1. Each of Hammock and Daré represents and warrants to the other, as of the date hereof, as follows:

6.2.1.1. Such party is a corporation, duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized and incorporated, with full power and authority to operate its properties and to carry on its business as presently conducted;

6.2.1.2. Such party has full power and authority to execute and perform this Agreement;

6.2.1.3. This Agreement constitutes the legally binding and valid obligation of such party, enforceable in accordance with its terms;

6.2.1.4. Such party's execution of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate corporate action;

6.2.1.5. Such party's execution and performance of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which such party is a party or by which it is bound (including the MilanaPharm Agreement);

6.2.1.6. Such party has obtained all necessary consents, approvals, and authorizations of all third parties required to be obtained by it in connection with the execution and performance of this Agreement;

6.2.1.7. There are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, administrative or legal proceedings pending or, to the knowledge of such party, threatened, against such party or its Affiliates, including with respect to administrative or other legal or governmental investigations, which could (a) be reasonably expected to affect or restrict the ability of such party to consummate the transactions under this Agreement and to perform its obligations under this Agreement, or (b) with respect to Hammock only, affect in any manner the Licensed Intellectual Property;

6.2.2. Hammock represents and warrants to Daré, as of the date hereof, as follows:

6.2.2.1. Hammock has the full right and legal capacity to assign the MilanaPharm agreement to Daré hereunder;

6.2.2.2. Neither Hammock nor any of its Affiliates has entered into any agreement or otherwise licensed, granted, assigned, transferred, conveyed or otherwise encumbered or disposed of any right, title or interest in or to any of its assets or intellectual property rights relating to any Licensed Intellectual Property other than this Agreement;

6.2.2.3. Immediately preceding the Effective Date, to its knowledge, Hammock was the exclusive licensee of the Licensed Intellectual Property Rights in the Field.

6.2.2.4. To the knowledge of Hammock, no Third Party is conducting or engaging in any activity that would constitute infringement or misappropriation of the Licensed Intellectual Property in the Field;

6.2.2.5. Neither Hammock nor any of its Affiliates has disclosed to any Person (other than the Licensors pursuant to the MilanaPharm Agreement), other than in the ordinary course of business consistent with past practice and pursuant to valid and enforceable written nondisclosure and limited use agreements, any proprietary or otherwise confidential information relating to the Licensed Intellectual Property, except where any such disclosure would not have an adverse impact on Hammock, the Licensed Intellectual Property or the assignment made to Daré under this Agreement; and

6.2.2.6. To Hammock's knowledge, (i) the Licensed Intellectual Property is valid and enforceable, (ii) no objection or proceeding is pending or threatened in writing that could reasonably be expected to affect the validity or enforceability of any patent issued or patent application pending pursuant to the Licensed Intellectual Property, and (iii) the Technology (in the form as delivered by Licensors to Hammock under the MilanaPharm Agreement) does not and will not infringe upon, conflict with, or misappropriate the subject matter of, any intellectual property of any third party.

6.2.2.7. To Hammock's knowledge (i) it has not withheld any information with respect to Hammock, the Licensors, the Technology and Data or the MilanaPharm Agreement in its control that would be material to a reasonable person's decision to enter into this Agreement, and (ii) all information disclosed by Hammock to Daré at any time prior to the Effective Date relating to the Licensed Intellectual Property and the MilanaPharm Agreement that would be material to a reasonable person's decision to enter into this Agreement is true and accurate.

6.3. Severability. If any term of this Agreement is held invalid or unenforceable for any reason, the remainder of the provisions will continue in full force and effect, and the parties will substitute a valid provision with the same intent and economic effect.

6.4. Applicable Law. This Agreement is governed by Delaware law, excluding its conflicts of law rules.

6.5. Entire Agreement. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and merges all prior and contemporaneous communications. It will not be modified except by a written agreement dated subsequent to the date of this Agreement and signed on behalf of the parties by their respective duly authorized representatives.

6.6. Notices. Any notice required or permitted to be given by this Agreement shall be in writing and shall be (a) delivered by hand or by overnight courier with tracking capabilities, or (b) mailed postage prepaid by first class, registered, or certified mail, in each case, addressed as set forth below unless changed by notice so given:

To Daré:
Dare Bioscience, Inc.
3655 Nobel Drive, Suite 260
San Diego, CA 92122
Attention: Chief Executive Officer

To Hammock:
Hammock Pharmaceuticals, Inc.
16700 Hammock Creek Place
Charlotte, North Carolina 28278
Attention: Chief Executive Officer

Any such notice shall be deemed given on the date received.

6.7. Assignment.

6.7.1. From and after the time all payments to Hammock have been made pursuant to Section 3, Daré may, upon notice to Hammock, assign this Agreement in its entirety to a third party.

6.7.2. From and after the time Hammock has substantially performed the Technology Transfer Plan, Hammock may, upon notice to Daré, assign this Agreement in its entirety to a third party.

6.7.3. Prior to the time referenced in the preceding clause (a) or (b) applicable to Daré or Hammock, such party shall not, without the prior written consent of the other party, assign or transfer any of its rights and obligations hereunder; *provided* that no such consent is required for such assignment or transfer by a party (A) to an Affiliate of such party or (B) to a successor-in-interest by reason of merger or consolidation of such party or sale of all or substantially all of the assets of such party to which this Agreement and, with respect to Daré only, the MilanaPharm Agreement relates; *provided further* that, with respect to an assignment or transfer by such party in accordance with the preceding clause (A) or (B), (i) with respect to an assignment to a successor-in-interest, such assignment includes all rights and obligations under this Agreement (and with respect to Daré, the MilanaPharm Agreement), (ii) such successor-in-interest or Affiliate shall have agreed as of such assignment or transfer to be bound by the terms of this Agreement in a writing provided to the other party, (iii) where this Agreement is assigned or transferred to an Affiliate, such assigning party remains responsible and liable for the performance of this Agreement, and (iv) where this Agreement is assigned or transferred by Daré to a successor-in-interest, the board of directors of Daré has reasonably determined, after consulting with Daré's chief financial officer and any experts deemed appropriate by the board, that such successor-in-interest has, and immediately after such assignment will have, sufficient financial assets to fulfill its obligations under this Agreement. Subject to the foregoing, this Agreement shall inure to the benefit of and be binding on the parties' successors and permitted assigns. Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning, non-transferring party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

6.8. Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but which collectively will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed effective as of the Effective Date.

DARÉ BIOSCIENCE, INC.	**HAMMOCK PHARMACEUTICALS, INC.**
By: /s/ Lisa Walters-Hoffert	By: /s/ William R. Maichle
Title: Chief Financial Officer	Title: CEO
Name: Lisa Walters-Hoffert	Name: William R. Maichle

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT A

MILANAPHARM AGREEMENT

[SEE ATTACHED]

EXCLUSIVE LICENSE AGREEMENT

This License Agreement (this "Agreement") is made effective as of January 9, 2017 ("Effective Date") by and among Hammock Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having its principal place of business at 16700 Hammock Creek Pl, Charlotte, NC 28278 ("Hammock"), and TriLogic Pharma, LLC a Delaware Limited Liability Corporation, having its principal place of business at 4 Peachwood Drive, Tallassee, AL 36078 ("TriLogic") and MilanaPharm LLC, a Delaware Limited Liability Corporation, having its principal place of business at 4 Peachwood Drive, Tallassee, AL 36078 ("MilanaPharm," and individually and collectively with TriLogic each a "Licensor" and together "Licensors"). Licensors and Hammock are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, TriLogic and MilanaPharm are parties to that certain License Agreement effective as of April 5, 2013 (the "TriLogic-MilanaPharm Agreement"), pursuant to which TriLogic Holders granted to MilanaPharm exclusive rights to certain Patent Rights and Know-How (as defined herein);

WHEREAS, Licensors own or Control (as defined herein) rights in certain Know-How; and

WHEREAS, Licensors desire to grant to Hammock, and Hammock desires to obtain from Licensors, an exclusive license (or sublicense as the case may be consistent herewith) under the Licensed Patents and Licensed Know-How (each as defined herein).

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. CERTAIN DEFINED TERMS

For purposes of this Agreement, the following terms when used with initial capital letters shall have the respective meanings set forth below in this Section 1 or elsewhere herein.

1.1. "Affiliate" means any Person that directly or indirectly is controlled by, controls, or is under common control with another Person. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast 50% or more of the votes in the election of directors, (b) in the case of a non-corporate entity, direct or indirect ownership of 50% or more of the equity interests with the power to direct the management and policies of such entity, or (c) any other arrangement whereby a Person controls or has the right to control the board of directors or equivalent governing body or management of a corporation or other entity; provided that, if Applicable Laws restrict foreign ownership, control shall be established by direct or indirect ownership of the maximum ownership percentage that may, under such Applicable Laws, be owned by foreign interests.

1.2. "Applicable Law" shall mean any federal, state, local or foreign law (including, common law), statute or ordinance, or any rule, regulation, judgment, order, writ or decree of or from any court, Regulatory Authority or other governmental authority having jurisdiction over or related to the subject item that may be in effect from time to time.

1.3. "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31; provided, however, that (a) the first Calendar Quarter of any particular period shall extend from the commencement of such period to the end of the first complete Calendar Quarter thereafter, and (b) the last Calendar Quarter shall end upon the expiration or termination of this Agreement.

1.4. "Clinical Trials" means Phase I clinical trials, Phase II clinical trials, Phase III clinical trials, and such other tests and studies in human subjects that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Licensed Product.

1.5. "Confidential Information" means subject to the exceptions in Section 5.2, all processes, formulae, data, Know-How, improvements, inventions, chemical or biological materials, chemical structures, techniques, reports, regulatory filings, correspondence, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by a Party, or has otherwise become known to a Party, or to which rights have been assigned to a Party, as well as any other information and materials that are deemed confidential or proprietary to or by a Party (including all information and materials of a Third Party held by a Party or its Affiliates under an obligation of confidentiality to such Third Party), in each case, that are disclosed by such Party or its Affiliates to the other Party or its Affiliates, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic, or electronic form.

1.6. "Controlled" or "Controls" means, when used in reference to an item or intellectual property rights, the legal authority or right of a Party (or any of its Affiliates) (whether by ownership or license) to grant the right to use such item or a license or sublicense of such intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to such other Party.

1.7. "Data" means any and all scientific, technical or test data pertaining to the Licensed Product that is generated by or on behalf of Hammock or its Affiliates or sublicensees or generated by or on behalf of Licensors or their Affiliates or sublicensees, including research data, clinical pharmacology data, CMC data (including analytical and quality control data and stability data), pre-clinical data, clinical data or submissions made in association with any Regulatory Filings (including any IND or NDA) with respect to the Licensed Product.

1.8. "EMA" means the European Medicines Agency and any successor agency or authority thereto.

1.9. "EU" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto.

1.10. "EU Major Markets" means the United Kingdom, France, Germany, Italy and Spain.

1.11. "FDA" means the United States Food and Drug Administration and any successor agency or authority thereto.

1.12. "Field" means the diagnosis, treatment and prevention, or supportive care of any human diseases, disorders, conditions, symptoms, or state of health or wellness in or through any intravaginal or urological applications, pathways or routes of administration.

1.13. "First Commercial Sale" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the date of the first sale for value by or on behalf of Hammock or any Affiliate or Sublicensee of Hammock to a Third Party of such Licensed Product for end use or consumption of such Licensed Product. First Commercial Sale excludes any sale or other distribution for use solely in a clinical trial or other development activity, reasonable and customary promotional use (including samples), or for compassionate use or on a named patient basis.

1.14. "Generic Product" shall mean, (i) with respect to a Licensed Product that is a pharmaceutical product (a) in the United States, any pharmaceutical product that is approved by the FDA and determined by the FDA to be therapeutically equivalent to the Licensed Product, as evidenced by a therapeutic equivalence code published in the Orange Book, or (b) in any other country or jurisdiction, any other pharmaceutical product that is recognized by the applicable Regulatory Authority in such country or jurisdiction as a generic drug or therapeutically equivalent to such Licensed Product, and (ii) with respect to a Licensed Product that is a device (a) in the United States, any device product that is approved by the FDA pursuant to a 510(k) or a Premarket Approval (PMA) premarketing authorization and determined by the FDA to be substantially equivalent to the Licensed Product, as evidenced in the FDA's database of "Device Approvals and Clearances" or applicable pricing compendium, or (b) in any other country or jurisdiction, any other device product that is recognized by the applicable Regulatory Authority in such country or jurisdiction as a generic device product or substantially equivalent to such Licensed Product, that, in the case of each of (i) and (ii) above, (A) has the same active ingredient(s), administration route, dosage form and strength as such Licensed Product and (B) is offered for sale or sold in such country or jurisdiction by a Third Party that is not a Sublicensee. Any product or component thereof (including any Licensed Product or component thereof) licensed, marketed, sold, manufactured or produced by a Party or its Affiliates or Sublicensees will not constitute a Generic Product.

1.15. "Initiation" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

1.16. "Know-How" means any and all data, inventions, methods, proprietary information, processes, trade secrets, techniques and technology, whether patentable or not but which are not generally known and have not been disclosed to third parties, including discoveries, formulae,

materials (including chemicals), biological materials, practices, test data, analytical and quality control data, and manufacturing technology data.

1.17. "Licensed Intellectual Property" means the Licensed Know-How and the Licensed Patents.

1.18. "Licensed Know-How" means all Know-How that is Controlled by either Licensor or its Affiliates as of the Effective Date or thereafter during the Term that is necessary or reasonably useful to practice under the Licensed Patents or otherwise relates to the Technology.

1.19. "Licensed Patents" means (a) the patents and patent applications (including provisional patent applications and PCT patent applications) Controlled by either Licensor or its Affiliates on the Effective Date relating to the Technology, including, the patents and patent applications listed in Appendix A; (b) all divisions, continuations and continuations-in-part of the foregoing applications; (c) all patents issuing from any of the foregoing applications, divisions, continuations and continuations-in-part; (d) any reissues, reexaminations, and extensions of any of the foregoing patents; and (e) all counterpart foreign and U.S. patent applications and patents to any of the foregoing.

1.20. "Licensed Product" means any product or process the development, making, having made, using, selling, offering for sale, lease or importation of which requires the use of any Licensed Know-How or, absent the license granted hereunder, would infringe one or more Valid Claims of the Licensed Patents, including, the Urology Product.

1.21. "Losses" means any claims, actions, demands, judgments, losses, damages, liabilities, costs or expenses (including reasonable attorneys' fees and expenses).

1.22. "MilanaPharm Product" means any product or process that would otherwise be deemed a Licensed Product if sold by Hammock or its Affiliates or Sublicensees, sold by or on behalf of MilanaPharm or its Affiliates or sublicensees solely for use outside of the Field.

1.23. "NDA" means a new drug application (as defined in the Act and applicable regulations promulgated thereunder by the FDA, as amended from time to time) (including a new drug application submitted pursuant to the requirements 21 U.S.C. § 355(b)(2) of the Act (a "505(b)(2) NDA")), with all additions, deletion or supplements thereto.

1.24. "Net Sales" means with respect to any Licensed Product, the gross amounts invoiced by a Selling Party from Third Party customers for sales of such Licensed Product, less the following deductions, to the extent such items are actually incurred, allowed, paid, accrued or specifically allocated or estimated in its financial statements in accordance with such Selling Party's accounting principles that are directly attributable to such sale in the market in which such sale occurred, (in each case, if not previously deducted from the amount invoiced) and consistent with customary business practices:

(a) discounts (including trade, quantity and cash discounts) cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to governmental entities or agencies, purchasers patients, reimbursers, distributors, wholesalers, customers, and group purchasing and managed care organizations or entities (and other similar entities and institutions);

(b) credits or allowances, on account of price adjustments, recalls, shelf-stock adjustments, justified claims of Third Party customers, rejections or returns of items previously sold (including Licensed Product returned in connection with recalls or withdrawals) (but excluding, in each case, where any such recall, claim, withdrawal, rejection or return arises out of a Selling Party's gross negligence, willful misconduct or fraud);

(c) reasonable allowance for uncollectible or bad debts;

(d) rebates (or their equivalent), administrative fees, chargebacks and retroactive price adjustments and any other similar allowances granted by a Selling Party (including to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and managed care organizations and entities (and other similar entities and institutions)) which effectively reduced the selling price or gross sales of the Licensed Product;

(e) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs incurred by a Selling Party in shipping Licensed Product to a Third Party, or amounts paid or payable to directly or indirectly to any Regulatory Authority; and

(f) import taxes, export taxes, excise taxes (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and other comparable laws), sales tax, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined and/or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind).

The calculations and deductions set forth in this Section 1.21 shall be determined in the ordinary course of business in accordance with historical practice and using the accrual method of accounting (as consistently applied by such Hammock, its Affiliates, and Sublicensees, as applicable); provided that any deductions for uncollectible or bad debts shall be further determined in accordance with generally accepted accounting principles consistently applied. Transfers of the Licensed Product among or between Hammock, its Affiliates, and Sublicensees for the purpose of subsequent resale to Third Parties will not generate Net Sales; with respect to such transfers, only the gross amounts invoiced in connection with the subsequent resale of the Licensed Product to Third Parties will be included in the calculation of Net Sales. Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Licensed Products, as applicable, for use in any Clinical Trial, non-clinical development activities with respect to Licensed Products by or on behalf of the Parties, for bona fide charitable purposes or for compassionate use or for reasonable and customary quantities of Licensed Product samples, if no consideration is received for such transfers. In the event consideration other than cash is paid to a Selling Party, for purposes of determining Net Sales, the Parties shall use the cash consideration that the Selling Party would realize from an unrelated buyer

in an arm's length sale of an identical item sold in the same quantity and at the time and place of the transaction, as determined jointly by Licensors and Hammock based on transactions of a similar type and standard industry practice, if any.

1.25. "Orange Book" means the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations.

1.26. "Other Technology Patent" means any patent applications or issued patents, other than the Licensed Patents, that come into the Control of either Licensor after the Effective Date that relates to the Technology and would prohibit or otherwise result in the infringement thereof by Hammock or its Affiliates or Sublicensees by their otherwise making, using, selling, offering for sale, or importation of a Licensed Product anywhere in the world pursuant to the terms of this Agreement.

1.27. "Patent Rights" means the rights and interests in and to issued patents and pending patent applications (including inventor's certificates and utility models) in any country or jurisdiction, including all provisionals, substitutions, continuations, continuations-in-part, divisionals, supplementary protection certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations, patents of addition thereof, PCTs, pediatric exclusivity periods and foreign equivalents to any of the foregoing.

1.28. "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association, or other entity.

1.29. "Regulatory Approval" means any and all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any national or international or local Regulatory Authority, department, bureau or other governmental entity, necessary for the manufacture and commercialization of a Licensed Product in any regulatory jurisdiction.

1.30. "Regulatory Authority" means, with respect to a country or region, any national (*e.g.*, the FDA for the United States), supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority involved in the granting of any approval required by Applicable Laws to manufacture and commercialize a relevant Licensed Product in such country or region or, to the extent required in such country or region, price approval, for pharmaceutical products in such country or region.

1.31. "Regulatory Filing" means any submission to a Regulatory Authority, including all applications, filings, submissions, approvals (including Regulatory Approvals and pricing and reimbursement approvals), licenses, registrations, permits, notifications and authorizations (or waivers) with respect to the testing, research, development, manufacture or commercialization of a product made to or received from any Regulatory Authority in a given country, together with any related correspondence and documentation submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to a product and all data contained in any of the foregoing, including any INDs and NDAs, regulatory drug lists,

advertising and promotion documents, clinical data, adverse event files and complaint files, and include any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto.

1.32. "Royalty Term" means, on a country-by-country and a Licensed Product-by-Licensed Product basis, the longer of (i) the expiration of the last Valid Claim of the Licensed Patents which cover the method of use of such Licensed Product in such country, or (ii) ten (10) years following the First Commercial Sale of such Licensed Product in such country.

1.33. "Selling Party" means Hammock, its Affiliates, and Sublicensees.

1.34. "Sublicensee" means any Third Party to whom Hammock grants a sublicense of some or all of the rights granted to Hammock under this Agreement in accordance with this Agreement.

1.35. "Sublicense Income" shall have the definition set forth in Section 4.2.3.

1.36. "Technology" means any and all hydrogel products, technologies, methods and processes Controlled by either Licensor based upon the drug delivery platform known as TRI-726 and all uses and applications thereof.

1.37. "Third Party" means any Person other than Hammock, MilanaPharm and their respective Affiliates.

1.38. "Urology Product" means any product for intraurological or endourological delivery using the TRI-726 drug delivery platform.

1.39. "USD" or $ means the lawful currency of the United States of America.

1.40. "Valid Claim" means a claim in an issued, unexpired patent within the Licensed Patents listed in any governmental registers in any country covering a Licensed Product which has received Regulatory Approval in such country, including, but not limited to, the Orange Book and the Canadian Patent Register, 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.

2. LICENSE GRANT

2.1. **License to Hammock**.

2.1.1. **Grant of License**. Each Licensor, on behalf of itself and its Affiliates, hereby grants to Hammock and its Affiliates an exclusive (even as to Licensors), royalty-bearing, non-transferable (except in accordance with Section 13.4) worldwide license, including the right to grant sublicenses (in accordance with Section 2.1.3), under the Licensed Intellectual Property, to research,

develop, make, have made, use, offer for sale, sell, import and commercialize Licensed Products, for any and all uses within the Field.

2.1.2. **Restrictions**. During the Term, neither Licensor nor any of its Affiliates will, directly or indirectly, (a) enter into any agreement or otherwise license, grant, assign, transfer, convey or otherwise encumber or dispose any right, title or interest in or to any of the Licensed Intellectual Property, which agreement, license, grant, assignment, transfer, conveyance, encumbrance or disposition would conflict with the rights granted to Hammock hereunder, or (b) research, develop, manufacture, register, use, market or otherwise commercialize any Licensed Products in or for the Field.

2.1.3. **Sublicensing**. Hammock may sublicense rights under this Agreement (including in multiple tiers of sublicenses) pursuant to written sublicense agreements, provided that:

(i) Hammock, within ten (10) days of the granting of each sublicense, notifying MilanaPharm of such grant and the name and address of each such Sublicensee;

(ii) The sublicense requiring the payment of royalty rates in an amount, when taken as a whole together with all other amounts to be paid by the applicable Sublicensee under such sublicense, that are at least reasonably sufficient to cover the amounts required to be paid to MilanaPharm under this Agreement for such Sublicensee's applicable sales;

(iii) the sublicense agreement (a) providing that the rights and/or obligations to MilanaPharm under Sections 4.5, 4.6, 5, 9.1, and 11 of this Agreement are binding upon the Sublicensee as if it were a party to this Agreement, and (b) including copies of such Sections or Articles;

(iv) the sublicense agreement including provisions of the same scope as provided in Sections 12 and 13;

(v) the sublicense agreement not containing any provision that could reasonably be deemed to cause any harm to MilanaPharm's rights hereunder or thereunder;

(vi) the sublicense agreement may permit the Sublicensee to grant further sublicenses, provided that such further sublicenses are (a) in writing, (b) consistent with the terms and requirements of this Agreement, and (c) include all provisions that Hammock is required to include in a sublicense;

(vii) the sublicense agreement disclaiming all representations, warranties, indemnities and liability on the part of Licensors;

(viii) the sublicense agreement not granting any rights to the Licensed Intellectual Property which are inconsistent with the rights granted to, and the obligations of, Hammock hereunder; and

(ix) Hammock shall remain responsible for the performance by the Sublicensee of such obligations.

2.1.4. **Marking**. Hammock will, and will use commercially reasonable efforts to require all Sublicensees to, mark (in a reasonable manner consistent with Applicable Law and/or industry custom and practice) all Licensed Products sold under the license granted in Section 2.1.1 with appropriate patent numbers or indicia (to the extent permitted by Applicable Law), in those countries in which (and only for so long as) such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of patents. This Section 2.1.4 shall expire, on a Licensed-Patent by Licensed-Patent basis upon expiration or cancellation of such Licensed Patent.

2.2. **Transfer of Know-How**.

2.2.1. Within thirty (30) days of the Effective Date, each Licensor, without additional consideration, shall disclose to Hammock all Licensed Know-How in existence as of the Effective Date. Such disclosures shall include all data, information and documents known to such Licensor which may be necessary or useful to Hammock to research, develop, manufacture, register, use, market or otherwise commercialize Licensed Products and practice the licenses granted hereunder efficiently. Each Licensor hereby covenants and agrees to provide reasonable assistance to Hammock or its designated Affiliate in connection with understanding and using the Licensed Know-How. Each Licensor will make available on a limited basis, at its own expense, the relevant individuals to effect the transfer of such Licensed Know-How. During the Term, each Licensor shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Hammock, in electronic form where possible, all Know-How that is necessary or reasonably useful to practice under the Licensed Patents, or that otherwise relates to the Technology, that comes into existence after the Effective Date and that was not previously provided to Hammock, promptly after the development, making, conception or reduction to practice of such Know-How.

2.2.2. During the Term, each Licensor shall cooperate with and provide reasonable assistance to Hammock or its designee, through documentation, consultation, training and face-to-face meetings, to enable Hammock or its designee in an efficient and timely manner to proceed with development, manufacturing and commercialization of the Licensed Products, including with respect to regulatory matters. In consideration for any technical transfer activities that require travel, the applicable Licensor will be compensated according to a rate and travel expenses budget to be pre-approved (in writing) by Hammock.

2.3. **Other Technology Patents.**

2.3.1. Licensors will promptly disclose to Hammock all developments and inventions (whether patentable or not) that (i) relate to the Technology; (ii) are conceived or reduced to practice by Licensors or otherwise come into the Control of a Licensor during the Term; and (iii) would constitute or legally be the subject of an Other Technology Patent. In the event that a Licensor considers and/or proceeds in seeking patent protection with respect to any such developments or inventions, such Licensor shall keep Hammock informed with respect thereto. Licensors shall

consider in good faith the requests and suggestions of Hammock with respect to strategies for filing and prosecuting the Licensed Patents.

2.3.2. Each Licensor, on behalf of itself and its Affiliates, hereby grants to Hammock the first option to include any Other Technology Patents within the scope of the exclusive license granted to Hammock pursuant to Section 2.1. This option will extend on an Other Technology Patent-by-Other Technology Patent basis for a time period of one (1) year from the date of its original disclosure of such Other Technology Patent to Hammock pursuant to Section 2.3.1 (the "Option Period"), and may be exercised by Hammock by providing written notice of such exercise to Licensors during such Option Period. In the event Hammock exercises such option with respect to an Other Technology Patent, promptly following such exercise, such Other Technology Patent shall automatically be deemed a Licensed Patent hereunder and the Parties shall amend Appendix A of this Agreement solely to include such Other Technology Patent within the scope of the exclusive license granted to Hammock hereunder without changing the economic terms of this Agreement. For clarity, prior to and during the Option Period for a particular Other Technology Patent, Licensors shall not assign, transfer, convey or grant any rights in or otherwise encumber such Other Technology Patent in any manner that would impair Hammock's rights in and to such Other Technology Patent.

2.3.3. All Data generated in connection with any research, development, regulatory, manufacturing or commercialization activities with respect to the Licensed Product conducted by or on behalf of Hammock or its Affiliates shall be the sole and exclusive property of Hammock ("**Hammock Data**").

2.3.4. Hammock will solely own all inventions and Patent Rights claiming such inventions, created, conceived in connection with any research, development, regulatory, manufacturing or commercialization activities with respect to the Licensed Product conducted by or on behalf of Hammock or its Affiliates ("**Hammock Inventions**"). Each Licensor shall, and hereby does, assign to Hammock all of such Licensor's right, title and interest in and to any Hammock Inventions and Patent Rights claiming such Hammock Inventions.

3. DEVELOPMENT AND COMMERCIALIZATION OF LICENSED PRODUCTS.

3.1. **Responsibility.** Hammock shall have the sole right and responsibility for developing and commercializing Licensed Products in the Field, at its sole cost and expense.

3.2. **Diligence.** Hammock shall use commercially reasonable efforts and resources that are consistent with those undertaken by it in pursuing the development and commercialization of other pharmaceutical products, taking into account regulatory, technical, legal, scientific, strategic, commercial, and/or medical factors (i), to develop and commercialize a Licensed Product in the Field in the United States and a Licensed Product in at least one of Canada or any country in the EU Major Market, or in the absence of any such other pharmaceutical products then such effort shall be assessed by reference to the efforts and resources customarily used in the industry by a company of similar size for a product with an equivalent sales and profit potential to the Licensed Product and (ii) following the First Commercial Sale of a Licensed Product in any country or

jurisdiction, to continue to commercialize such Licensed Product in such country or jurisdiction. Hammock may satisfy the foregoing obligation itself or through its Affiliates or Sublicensees.

3.3. **Regulatory Activities.** Promptly following the Effective Date (and in any event within thirty (30) days after the Effective Date), each Licensor shall and hereby does assign and transfer all of such Licensor's Data and Regulatory Filings for the Licensed Product in the Field in the Territory to Hammock. Hammock shall be solely responsible for formulating regulatory strategy and for preparing, filing, and obtaining any Regulatory Approvals for the Licensed Product in the Field in the Territory. Hammock shall be the holder of all Regulatory Approvals for the Licensed Product in the Field in the Territory and shall have responsibility for maintaining such Regulatory Approval and for interactions with Regulatory Authorities with respect to the Licensed Product in the Field in the Territory.

3.4. **Hammock Data**. Subject to Section 4.7, Hammock shall provide Licensors with copies of all of Hammock Data as such Hammock Data becomes available and hereby grants to Licensors a non-exclusive, non-transferable (except pursuant to Section 13.4), royalty-bearing license to use the Hammock Data solely for use outside of the Field, including associated regulatory activities, subject to the rights granted to Hammock for the MilanaPharm Product in the Field in the Territory. Licensors will not, and will cause its respective sublicensees to not, modify, manipulate, misrepresent or omit any material data or facts in connection with their use of the Hammock Data.

3.5. **Pricing.** Hammock shall have sole control over the pricing and discounts for all Licensed Products in the Field. Notwithstanding the foregoing, if a Selling Party shall sell a Licensed Product to a customer who also purchases other products or services from any such entity, Hammock agrees not to, and to require its other Selling Parties not to, manipulate the discount or price of any Licensed Product for the purpose of circumventing of reducing the royalty obligations hereunder in a manner that is intended to materially disadvantage the royalty payable for the sale of such Licensed Product to benefit sales or prices of such other products offered for sale by such Selling Party.

3.6. **Reports**. With respect to each Licensed Product, Hammock shall provide to MilanaPharm every six months a summary report which shall set forth the results of the development work and regulatory activities performed during the preceding year and summarize the activities planned for the coming year. Such reports shall be prepared by Hammock and provided to MilanaPharm within sixty (60) days after the end of each six month period and shall include status or results of any Clinical Trials, when applicable.

4. PAYMENTS

4.1. **Initial Payment.** Within ten (10) business days following the Effective Date, Hammock shall pay to MilanaPharm a one-time payment of [***] dollars ($[***]).

4.2. **Milestone Payments**.

4.2.1. **Milestones**. Subject to the terms and conditions set forth in this Agreement, Hammock shall pay to MilanaPharm a milestone payment within [***] ([***]) days after the achievement of each of the following milestones in the Field, calculated as follows:

(i) Upon [***]: [***]dollars ($[***]); and

(ii) Upon [***]: [***]dollars ($[***]); and

(iii) Upon [***]: [***]dollars ($[***]); provided, that if the [***], then such milestone payment shall be payable as follows, [***]dollars ($[***]) upon such [***], and then the remaining [***] ($[***]) upon [***]; and

(iv) Upon [***] different from the Licensed Product in Section 4.2.1(iii) above and different from any Licensed Product for which a milestone was previously paid under this Section 4.2.1(iv): [***] dollars ($[***]); provided, that if the [***], then such milestone payment shall be payable as follows: [***]dollars ($[***]) upon such [***], and then the remaining [***] dollars ($[***]) upon [***]; and

(v) Upon [***]: [***]dollars ($[***]); provided, that if [***], then such milestone payment shall be payable as follows, [***] dollars ($[***]) upon such [***], and then the remaining [***] dollars ($[***]) upon such [***]; and

(vi) Upon [***] different from the Licensed Product in Section 4.2.1(v) above and different from any Licensed Product for which a milestone was previously paid under this Section 4.2.1(vi): [***] dollars ($[***]); provided, that if the [***], then such milestone payment shall be payable as follows: [***] dollars ($[***]) upon such [***], and then the remaining [***] dollars ($[***]) upon such [***].

4.2.2. **Out-License Milestone Payment.** Subject to the terms and conditions set forth in this Agreement, Hammock shall pay to MilanaPharm an out-license milestone payment of [***] dollars ($[***]) in the event that Hammock or an Affiliate of Hammock shall grant a sublicense under any of its rights to the Licensed Intellectual Property to a Third Party (excluding any sublicense solely for any Clinical Trial or non-clinical development activities with respect to Licensed Products by or on behalf of any Selling Party, in each case, if no consideration is received by Hammock or its Affiliate for the grant of such sublicense) prior to the payment by Hammock to MilanaPharm pursuant to Section 4.2.1 above of an aggregate of at least [***] dollars ($[***]). Such payment to MilanaPharm hereunder to be made within [***] ([***]) days after the closing of such Third Party sublicense.

4.2.3. **Foreign Sublicense Income**. Subject to the terms and conditions set forth in this Agreement, Hammock shall pay to MilanaPharm [***] percent ([***]%) of all Foreign Sublicense Income. For the purposes of this Section 4.2.3, "Foreign Sublicense Income" shall mean income that is received by Hammock or an Affiliate of Hammock in connection with the sublicense under any of the Licensed Intellectual Property to a Third Party Sublicensee for use outside of the United States. Foreign Sublicense Income includes amounts received from a Sublicensee in the

form of license issue fees, milestone payments, royalties and similar payments but specifically excludes (a) any royalties on the sale or distribution of Licensed Products for which a payment to MilanaPharm of royalties pursuant to Section 4.3.1 below is being made, (b) the reasonable fair market consideration received for the purchase of equity in Hammock or its Affiliates calculated without regard to any sublicense granted for such Licensed Intellectual Property, (c) reasonable and customary payments for research and development services (including any sublicense solely for any Clinical Trial or non-clinical development activities with respect to Licensed Products by or on behalf of any Selling Party, (d) amounts received in consideration of the grant of a license or sublicense under intellectual property rights other than the Licensed Intellectual Property so long as such amounts are not greater than the reasonable value of such granted rights relative to the value attributed to the Licensed Intellectual Property sublicensed, (e) amounts received in connection with the achievement of a particular milestone subject to payment to MilanaPharm as a Milestone Payment under Section 4.2.1 of this Agreement, and (f) any amounts received by Hammock or its Affiliates in connection with a grant of a sublicense for use in the United States. Such payment to MilanaPharm hereunder to be made within [***] ([***]) days after the receipt by Hammock of its Affiliate of any such Sublicense Income.

4.3. **Royalty Payments**.

4.3.1. **Royalty Rates**. Subject to the terms and conditions set forth in this Agreement, including, the terms of Sections 4.3.2, 4.3.3, 4.3.4, and 4.3.5, Hammock will pay to MilanaPharm a royalty equal to [***] percent ([***]%) on the Net Sales of each Licensed Product during the Royalty Term. Royalties shall be paid under this Section 4.3.1, on a country-by-country and Licensed Product-by-Licensed Product basis, on Net Sales of each Licensed Product made from the First Commercial Sale of such Licensed Product in each country during the Royalty Term applicable to such Licensed Product.

4.3.2. **Reduction for No Valid Claim**. The royalty amounts payable with respect to Net Sales of Licensed Products shall be reduced in the United States and on a Licensed Product-by-Licensed Product basis by [***] percent ([***]%) during any portion of the Royalty Term during which such Licensed Product is not covered by at least one Valid Claim of the Licensed Patents in the United States.

4.3.3. **Generic Competition**.

(i) On a Licensed Product-by-Licensed Product and country-by-country basis, if one Generic Product is launched in a country during the Royalty Term, the royalty rate set forth in Section 4.3.1 will be reduced to [***] percent ([***]%) in such country following such generic launch.

(ii) On a Licensed Product-by-Licensed Product, and country-by-country basis, if a second Generic Product is launched in a country during the Royalty Term, the royalty rate set forth in Section 4.3.1 will be reduced to [***] percent ([***]%) in such country following such generic launch.

(iii) On a Licensed Product-by-Licensed Product, and country-by-country basis, if a third Generic Product is launched in a country during the Royalty Term, [***].

4.3.4. **Third Party Payments**.

(i) MilanaPharm shall remain responsible for the payment of royalty, milestone and other payment obligations due to TriLogic under the TriLogic-MilanaPharm Agreement. All such payments shall be made promptly by MilanaPharm in accordance with the terms of the TriLogic-MilanaPharm Agreement.

(ii) In the event that Hammock reasonably determines after consultation with MilanaPharm that rights to Patent Rights, Know-How or other intellectual property owned or controlled by a Third Party are required to exercise the licenses granted to Hammock hereunder, Hammock shall have the right to negotiate and acquire such rights through a license or otherwise and to deduct from the then-current payments due to MilanaPharm the amounts paid (including milestone payments, royalties or other license fees) by Hammock to such Third Party; provided, however, that in no event shall the amounts due to MilanaPharm from Hammock in any Calendar Quarter be reduced by more than [***] percent ([***]%). Any amount that Hammock is entitled to deduct that is reduced by the foregoing limitation on the deduction, or is otherwise not deducted in a particular Calendar Quarter (for example, if the amount due to MilanaPharm is less than the amount due to such Third Party during such Calendar Quarter), such amount that was not deducted shall be carried forward for up to [***] ([***]) Calendar Quarters, and Hammock may deduct such remaining and unexpired amount from subsequent amounts due to MilanaPharm until the full amount that Hammock was entitled to deduct is deducted. Each Licensor shall cooperate with Hammock to acquire such rights at its reasonable request and expense.

4.3.5. **Patent Prosecution Expenses**. In the event that Hammock incurs any expenses from the preparation, filing, prosecution or maintenance of any patents pursuant to Section 6.2, Hammock shall deduct from the then-current payments due to MilanaPharm up to [***] percent ([***]%) of the amounts paid (including milestone payments, royalties or other license fees) by Hammock for the preparation, filing, prosecution or maintenance of such patents; provided, however, that in no event shall the amounts due to MilanaPharm from Hammock in any Calendar Quarter be reduced by more than [***] percent ([***]%).

4.4. **Payment Terms**.

4.4.1. **Payment of Royalties**.

(i) Hammock shall make royalty payments owed to MilanaPharm hereunder in arrears, within [***] ([***]) days from the end of each Calendar Quarter in which such payment accrues. Each royalty payment shall be accompanied by a report for each country in which sales of Licensed Products occurred in the Calendar Quarter covered by such statement, containing information sufficient to calculate the royalty payable on a country-by-country basis, including all amounts included in the calculation of Net Sales, a breakdown of specific deductions taken in such calculation, amounts from all Affiliates and Sublicensees.

(ii) Within [***] ([***]) days after the end of each Calendar Quarter during the Royalty Term, Hammock shall perform a "true up" reconciliation (and shall provide MilanaPharm with a written report of such reconciliation) of the deductions outlined in subsection (a) through (f) in the definition of "Net Sales." The reconciliation shall be based on actual cash paid or credits issued plus an estimate for any remaining liabilities incurred related to the product, but not yet paid. If the foregoing reconciliation report shows either an underpayment or an overpayment between the Parties, the Party owing payment to the other Party shall pay the amount of the difference to the other Party within [***] ([***]) days after the date of delivery of such report.

(iii) Within [***] ([***]) months after the expiration or earlier termination of this Agreement, Hammock shall perform a "true-up" reconciliation (and shall provide Licensor with a written report of such reconciliation) of the items comprising deductions from Net Sales for returns as outlined in subsection (b) in the definition of "Net Sales." The reconciliation shall be based on actual cash paid or credits issued for returns, through the [***] ([***]) month period following the termination or expiration of this Agreement. If the foregoing reconciliation report shows either an underpayment or an overpayment between the Parties, the Party owing payment to the other Party shall pay the amount of the difference to the other Party within [***] ([***]) days after the date of delivery of such report.

(iv) Each Calendar Quarter during the Royalty Term, Hammock shall perform a "true up" reconciliation (and shall provide MilanaPharm with a written report of such reconciliation of any such reconciliation) of any Net Sales royalty payments owed to MilanaPharm under this Section 4.3 in excess of any costs and expenses (including reasonable attorneys' fees and costs) incurred in prosecuting any action under Section 7.2. If the foregoing reconciliation report shows any excess Net Sales income that is in excess of such litigation fees and expenses incurred in such Calendar Quarter, Hammock shall make all royalty payments properly payable to MilanaPharm on such excess Net Sales within [***] ([***]) days after the date of delivery of such report. In the event that such litigation fees and expenses exceeds the Net Sales for such Calendar Quarter, than no royalty payment shall be due for such Calendar Quarter. Hammock shall be entitled to carry over all excess litigation fees and expenses and may deduct such remaining amounts from subsequent amounts due to MilanaPharm until the full amount that Hammock was entitled to deduct is deducted.

4.4.2. **Tax Withholding; Restrictions on Payment**. MilanaPharm will pay any and all taxes levied on account of all payments it receives under this Agreement. If laws, regulations or rules require that taxes be withheld with respect to any payments by Hammock to MilanaPharm under this Agreement, Hammock shall provide MilanaPharm, prior to any such payment, annually or more frequently if required, with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary and: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to MilanaPharm on a timely basis following that tax payment. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with Applicable Laws, regulations and rules. In addition, the Parties shall cooperate

in accordance with Applicable Laws, regulations and rules and use reasonable efforts to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement.

4.4.3. **Payment Method**. All amounts due to MilanaPharm under this Agreement will be paid in U.S. dollars, by wire transfer in immediately available funds to an account designated in writing by MilanaPharm. Any payment not delivered on time shall accrue interest from the date due until paid in full at the rate of the lower of 1.0% per month or the highest rate allowed under applicable laws; provided that no interest shall accrue on any amounts being disputed in good faith by Hammock with respect to which Hammock is making diligent and good faith efforts to resolve.

4.5. **Royalty Records**. Hammock and its Affiliates and Sublicensees shall keep, for at least [***] ([***]) years from the end of the calendar year to which they pertain, complete and accurate records of sales by Hammock, its Affiliates and Sublicensees, as the case may be, of each Licensed Product, in sufficient detail to allow the accuracy of the payments hereunder to be confirmed.

4.6. **Review**. Subject to the other terms of this Section 4.6, at the request of MilanaPharm, which shall not be made more frequently than once per calendar year during the Term, upon reasonable prior written notice, and at MilanaPharm's expense, Hammock shall permit an independent certified public accountant selected by MilanaPharm and reasonably acceptable to Hammock to inspect (during regular business hours) the records required to be maintained by Hammock relating to royalties payable pursuant to this Agreement. In every case the accountant must have previously entered into a confidentiality agreement with all Parties substantially similar to the provisions of Section 5 and limiting the disclosure and use of such information by such accountant to authorized representatives of the Parties and the purposes germane to this Section 4.6. The Parties shall treat the results of any such accountant's review of such records under this Section 4.6 as Confidential Information of the applicable Party subject to the terms of Section 5. If any review reveals a deficiency in the calculation and/or payment of royalties by Hammock, then (a) Hammock shall promptly pay MilanaPharm the amount remaining to be paid, and (b) if such underpayment is of more than the greater of (i) $30,000 or (ii) ten percent (10%) for any twelve (12) month consecutive period, Hammock shall, within thirty (30) days of invoice therefor, pay the reasonable out-of-pocket costs and expenses incurred by MilanaPharm in connection with the review.

4.7. **MilanaPharm Products.** MilanaPharm will pay Hammock fifteen percent (15%) of all income, royalties, milestones, and other payments and other amounts, received by any Licensor, its Affiliates or sublicensees for the sale or other exploitation of MilanaPharm Products, or sublicensing of any of the Hammock Data, outside of the Field for which such Licensor, its Affiliates or sublicensees materially uses, relies on, references or incorporates any Hammock Data for purposes of seeking or obtaining Regulatory Approval for such MilanaPharm Products. The terms of Sections 4.4 and 4.5 shall apply to MilanaPharm, *mutatis mutandis*.

4.8. **Currency**. Payments under this Agreement shall be made in USD. All royalties payable shall be calculated first in the currency of the jurisdiction in which payment was made, and if not in the United States, then converted into USD. The exchange rate for such conversion shall be the

average of the rate quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter for such royalty payment made.

5. CONFIDENTIALITY

5.1. **Confidential Obligations**. Each Party agrees that a Party (the "Receiving Party") receiving Confidential Information of the other Party (the "Disclosing Party") (or that has received any such Confidential Information from the other Party prior to the Effective Date) shall, subject to Section 5.2 and Section 5.3, (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary industrial information of similar kind and value, but in no circumstances less than a reasonable standard of care, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those expressly permitted by this Agreement (it being understood that this clause (c) shall not create or imply any rights or licenses not expressly granted under this Agreement).

5.2. **Exceptions**. The obligations in Section 5.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent written proof:

(i) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party by or on behalf of the Disclosing Party;

(ii) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(iii) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(iv) is published by a Third Party or otherwise becomes publicly available or enters the public domain without violation of this Agreement by the Receiving Party, either before or after it is disclosed to the Receiving Party; or

(v) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon the Disclosing Party's Confidential Information.

5.3. **Authorized Disclosure**. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party, and Confidential Information deemed to belong to both Parties under the terms of this Agreement, to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(i) subject to Section 5.5, complying with Applicable Laws (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange)

and with judicial or administrative process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;

(ii) disclosure by the Receiving Party of the existence of this Agreement in any press release, annual or special report to stockholders, filings with the Securities and Exchange Commission and other Regulatory Authorities and communications with securities analysts and stockholders; and

(iii) disclosure, solely on a "need to know basis," to Affiliates, potential or actual research and development collaborators, subcontractors, investment bankers, investors, lenders, shareholders, or other potential financial partners, and their and each of the Parties' respective directors, employees, contractors, agents, legal counsel and accountants, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 5, which for avoidance of doubt, will not permit use of such Confidential Information for any purpose except those permitted by this Agreement; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 5.3 to treat such Confidential Information as required under this Article 5.

If and whenever any Confidential Information is disclosed in accordance with this Section 5.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and subject to Section 5.5, the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make any disclosures pursuant to Section 5.3(i) sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information, and the Receiving Party will provide reasonable assistance to the Disclosing Party with respect thereto; provided that, in any event, the Receiving Party will use reasonable measures to ensure confidential treatment of such information and shall only disclose such Confidential Information of the Disclosing Party as is necessary to comply with such Applicable Laws or judicial process.

5.4. **Terms of this Agreement**. The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties.

5.5. **Securities Filings**. If either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other Applicable Law, the Party shall notify the other Party of such intention and shall provide such other Party with a copy of relevant portions of the proposed filing prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to the terms and conditions of this Agreement, and shall use reasonable and diligent efforts to obtain confidential treatment of the terms and conditions of this Agreement that such other Party requests be kept confidential, and shall only disclose

Confidential Information that is requested by the Securities and Exchange Commission or legally required to be disclosed. No such notice shall be required under this Section 5.5 if the description of or reference to this Agreement contained in the proposed filing has been included in the Press Release or in any previous filing made by the either Party hereunder or otherwise approved by the other Party.

5.6. **Publicity**. Except as set forth in this Agreement or as required by law, neither Party shall make any press release or other public announcement or other disclosure to a Third Party concerning the existence of or terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Each Party agrees to provide to the other Party a copy of any public announcement as soon as reasonably practicable under the circumstances prior to its scheduled release. Each party shall have the right to expeditiously (but in any event within twenty-four (24) hours of receipt) review any press release or announcement regarding this Agreement or the subject matter of this Agreement; provided, however, that such right of review shall only apply for the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar information that has previously been disclosed unless there have been material changes in the disclosure since the date of the previous disclosure.

6. PATENT PROSECUTION AND PATENT LISTING

6.1. **Prosecution**. As between Licensors and Hammock, MilanaPharm shall have the first right to prepare, file, prosecute and maintain the Licensed Patents during the term of this Agreement, at MilanaPharm's sole cost and expense. Licensors shall keep Hammock fully informed of all steps with regard to the preparation, filing, prosecution, and maintenance of the Licensed Patents, including by providing Hammock with a copy of material communications to and from the applicable patent authority regarding such Licensed Patents, and by providing Hammock drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Hammock to review and comment thereon. MilanaPharm shall take all reasonable comments made by, and otherwise act in accordance with instructions provided by, Hammock on matters related to prosecution, maintenance and enforcement related to the Licensed Patents.

6.2. **Decision Not to Prosecute**. In the event that MilanaPharm decides not to prepare, file, prosecute, or maintain any Licensed Patent in any country or jurisdiction, MilanaPharm shall provide reasonable prior written notice to Hammock of such intention (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Licensed Patent in such country or jurisdiction). Hammock shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Licensed Patent at its expense in such country or jurisdiction, and such amounts shall be deducted from amounts due to MilanaPharm pursuant to Section 4.3.5. As of the Effective Date, MilanaPharm acknowledges that Hammock shall have the right to assume sole control and direction of the preparation, filing, prosecution and maintenance of U.S. Patent Application No. 62/194,518 and all Patent Rights issuing from or claiming priority to such U.S. Patent Application.

6.3. **Third-Party Rights**. Subject to Section 4.3.4(ii), in the event that either Licensor and/or their respective Affiliates licenses or acquires any Patent Rights, Know-How or other intellectual property rights from one or more Third Parties required for the commercialization of any Licensed Product by Hammock, such Licensor and/or Affiliates shall ensure that such license or acquisition permits such rights to be granted, licensed or sublicensed to Hammock, as necessary, and such Licensor shall, or shall cause such Third Party to, grant to Hammock such license or sublicense.

6.4. **Orange Book Listings**. Hammock will have the sole right, after consultation with MilanaPharm, to determine which, if any, of the Licensed Patents should be listed in any governmental registers in any country requiring or permitting a listing of patents covering a Licensed Product which has received Regulatory Approval in such country, including, but not limited to, the Orange Book and the Canadian Patent Register. Hammock will have the sole right to make any such filings and listings, and will have sole responsibility for any and all decisions with respect to such filings and listings. Licensors shall reasonably cooperate with Hammock and shall provide Hammock with all reasonably requested documents and information necessary for Hammock to make such filings and listings.

7. PATENT ENFORCEMENT

7.1. **Notice of Infringement**. If either Party determines that any claim to a Licensed Patent is being infringed by a Third Party's activities, and that such infringement could affect the exercise of the license under this Agreement ("Infringement"), it will promptly notify the other Party in writing. In addition, if a Party determines that any Licensed Know-How is being misappropriated by a Third Party's activities and that such misappropriation could affect the exercise of the license under this Agreement, it will promptly notify the other Party in writing and provide the other Party with available evidence of such Infringement.

7.2. **Enforcement Rights**. Hammock shall have the first right (but not the obligation) to seek to abate or to file suit against any such Third Party with respect to any Infringement of the Licensed Patents in the Field. Licensors shall reasonably cooperate with Hammock in any such suit, including, if necessary, by being, and Licensors hereby agree to be, joined as a party, and Hammock shall keep Licensors updated with respect to any such action, including providing copies of all material documents received, prepared or filed in connection with any such action. In the event that Hammock declines to pursue its rights under this Section 7.2, MilanaPharm, at its own cost and expense, may (but will not be obligated) to seek to abate or to file suit against any such Third Party with respect to any Infringement of the Licensed Patents. In the event MilanaPharm exercises its rights pursuant to this Section 7.2, Hammock shall reasonably cooperate with MilanaPharm in any such suit, including, if necessary, by being, and Hammock hereby agrees to be, joined as a party, and MilanaPharm shall keep Hammock updated with respect to any such action, including providing copies of all material documents received, prepared or filed in connection with any such action. Hammock shall have the right to enter into a settlement of any matter under this Section 7.2, without Licensors' consent, so long as (a) such settlement does not involve any express statement or admission of any fault of, breach of contract by, or violation of Applicable Law by, MilanaPharm, (b) MilanaPharm is not liable under such settlement agreement to pay any monetary damages or other payments, for which Hammock shall agree not to seek any

indemnification from MilanaPharm, and does not include any requirement that MilanaPharm take or refrain from taking any actions other than compliance with any nondisclosure obligations related to the terms of such settlement contained in the settlement agreement, (c) such settlement includes a release of MilanaPharm on the same terms as such release applies to Hammock, (d) such settlement agreement includes a reasonable confidentiality obligation by the Third Party claimant or defendant of the terms of the settlement, and (e) to the extent MilanaPharm is not a direct signatory of such settlement agreement, MilanaPharm is designated as an express third party beneficiary of the settlement agreement, entitled to enforce the applicable terms of such settlement agreement; in any other event, Licensors' consent shall be required (such consent not to be unreasonably withheld, conditioned or delayed).

7.3. **Allocation of Recoveries**. If either Party or its designee files a suit, action or proceeding against an actual, alleged or threatened Infringement, then any damages, monetary awards or other amounts recovered by such Party or its designee, whether by judgment or settlement, shall be applied as follows:

(i) First, to reimburse such Party and its designees (if applicable) for costs and expenses (including reasonable attorneys' fees and costs) incurred in prosecuting such enforcement action;

(ii) Second, to reimburse the other Party for costs and expenses (including reasonable attorneys' fees and costs) incurred in assisting in the prosecution of such enforcement action at the request of such Party;

(iii) Third, any remaining amount that represents compensation for lost sales, a reasonable royalty or lost profits, shall be retained by or paid to Hammock; provided, however, any such amount (after relevant adjustment to convert to Net Sales of Licensed Products) shall be subject to the royalty obligations set forth in Section 4.3; and

(iv) Fourth, any remaining amount that represents additional damages (e.g., enhanced or punitive damages) shall be shared equally by the Parties.

7.4. **Certain Limitations**. Neither Party shall (or permit any of its licensees or sublicensees to) knowingly take any position with respect to, or compromise or settle, any action involving the enforcement of any Licensed Patents in any way that would be reasonably likely to directly and adversely affect their scope, validity or enforceability without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

8. REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1. **Licensor Representations**. Each Licensor represents and warrants to Hammock, as of the date hereof, as follows.

8.1.1. Such Licensor is a limited liability company, validly existing and in good standing under the laws of the country in which it is organized, with full power and authority to operate its properties and to carry on its business as presently conducted;

8.1.2. Such Licensor has full power and authority to execute, deliver and perform this Agreement;

8.1.3. Such Licensor has the full right and legal capacity to grant the rights granted to Hammock hereunder;

8.1.4. This Agreement constitutes the legally binding and valid obligation of such Licensor, enforceable in accordance with its terms;

8.1.5. The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate limited liability company action;

8.1.6. The execution, delivery and performance by such Licensor of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which such Licensor is a party or by which it is bound (including the TriLogic-MilanaPharm Agreement);

8.1.7. There is no action, suit, proceeding or investigation pending or, to the knowledge of such Licensor, currently threatened in writing against or affecting such Licensor that questions the validity of this Agreement or the right of such Licensor to enter into this Agreement or consummate the transactions contemplated hereby;

8.1.8. Except for the patents and patent applications set forth on Appendix A, neither such Licensor nor any of its Affiliates Controls any Patent Rights that cover or relate to the Technology or Licensed Product, or that otherwise are necessary or beneficial for the production, use, research, development, manufacture or commercialization of Licensed Products in the Field;

8.1.9. Except for the TriLogic-MilanaPharm Agreement, such Licensor is not a party to any agreement that relates to the Licensed Patents, Licensed Know-How, or Hammock's rights under this Agreement. Such Licensor has provided to Hammock a complete and accurate copy of the TriLogic-MilanaPharm Agreement, including all amendments, addendums, and exhibits. The TriLogic-MilanaPharm Agreement is legal, valid, binding, enforceable, and in full force and effect and such Licensor or its Affiliates has performed all obligations imposed upon it thereunder and is not in breach thereof, and, to the best of its knowledge, no other party to the TriLogic-MilanaPharm Agreement is in breach thereof. Such Licensor and its Affiliates have not received

any notice that the other parties to the TriLogic-MilanaPharm Agreement intend to cancel, terminate or refuse to renew the same or to exercise or decline to exercise any option or right thereunder. The consummation of the transactions contemplated hereby will not cause a breach of the TriLogic-MilanaPharm Agreement;

8.1.10. Neither such Licensor nor any of its Affiliates has entered into any agreement or otherwise licensed, granted, assigned, transferred, conveyed or otherwise encumbered or disposed of any right, title or interest in or to any of its assets or intellectual property rights relating to any Licensed Intellectual Property;

8.1.11. There are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, administrative or legal proceedings pending or, to the knowledge of such Licensor, threatened against such Licensor or its Affiliates, including with respect to administrative or other governmental investigations, which would (a) be reasonably expected to affect or restrict the ability of such Licensor to consummate the transactions under this Agreement and to perform its obligations under this Agreement, or (b) affect in any manner the Licensed Intellectual Property or such Licensor's Control thereof;

8.1.12. To the knowledge of such Licensor, no Third Party is conducting or engaging in any activity that would constitute infringement or misappropriation of the Licensed Intellectual Property in the Field;

8.1.13. Neither such Licensor nor any of its Affiliates has disclosed to any Person (other than the other Licensor pursuant to the TriLogic-MilanaPharm Agreement), other than in the ordinary course of business, consistent with past practice and pursuant to valid written non-disclosure and non-use agreements, which are enforceable by such Licensor or its Affiliates, any proprietary or otherwise confidential information relating to the Licensed Intellectual Property, except where any such disclosure would not have adverse impact on such Licensor, the Licensed Intellectual Property or the rights granted to Hammock under this Agreement. Such Licensor has at all times maintained reasonable procedures to protect its Confidential Information and the Licensed Intellectual Property; and

8.1.14. Except as set forth on Schedule 8.1.14, to such Licensor's best knowledge after reasonable due diligence and inquiry, (i) the Licensed Intellectual Property is valid and enforceable, (ii) no objection or proceeding is pending or threatened that could reasonably be expected to affect the validity of any patent issued or patent application pending pursuant to the Licensed Intellectual Property, and (iii) the Technology (in the form as delivered by Licensors to Hammock under this Agreement) does not and will not infringe upon, conflict with, or missapropriate the subject matter of, any intellectual property of any Third Party.

8.2. **Hammock's Representations**. Hammock represents and warrants to Licensors, as of the date hereof, that:

8.2.1. Hammock is a corporation, duly incorporated, validly existing and in good standing under the laws of the state in which it is organized, with full corporate power and authority to operate its properties and to carry on its business as presently conducted;

8.2.2. Hammock has full power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legally binding and valid obligations of Hammock, enforceable in accordance with their terms;

8.2.3. the execution, delivery and performance by Hammock of this Agreement and the consummation of the transactions contemplated thereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement material to Hammock, its business or assets;

8.2.4. no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of Hammock is required in connection with the execution, delivery and performance of this Agreement; and

8.2.5. there is no action, suit, proceeding or investigation pending or, to the knowledge of Hammock, currently threatened against or affecting Hammock or that questions the validity of this Agreement, or the right of Hammock to enter into this Agreement or consummate the transactions contemplated hereby.

8.3. **Covenants**.

8.3.1. Each Licensor covenants and agrees that during the Term, it, or its Affiliates, will not take any action or cause or permit the taking of any action that would have the effect of invalidating or breaching any of the representations or warranties contained in Section 8.1 (as of the date when such representation or warranty was made or, if made as of a specified date, as of such specified date), including, any action that would result in any encumbrance on the Licensed Intellectual Property, the invalidity of any Patent Right, the grant of any license or right relating to the Licensed Intellectual Property to any Third Party, the transfer or disposal of any Licensed Intellectual Property, or otherwise materially adversely affect the rights of Hammock under this Agreement.

8.3.2. During the Term, each Licensor shall comply with and maintain in full force the TriLogic-MilanaPharm Agreement and shall not amend or modify the TriLogic-MilanaPharm Agreement in a manner that would materially affect the license or rights granted to Hammock hereunder without the prior written consent of Hammock. Each Licensor shall promptly provide written notice to Hammock describing any breach, alleged breach or potential breach of the TriLogic-MilanaPharm Agreement of which it becomes aware and provide Hammock with copies of any correspondence related thereto. Each Licensor will promptly notify Hammock of any facts or circumstances indicating that it may be unable to cure an existing, alleged or potential breach of the TriLogic-MilanaPharm Agreement, providing notification as soon as possible and in no event later than the date on which fifty percent (50%) of the relevant cure period has elapsed.

Notwithstanding anything to the contrary in this Agreement or in the TriLogic-MilanaPharm Agreement, any failure or breach by MilanaPharm to make any payments under the TriLogic-MilanaPharm Agreement shall not be deemed a breach by, or attributable to, Hammock and shall otherwise have no impact on this Agreement or any of the rights granted to Hammock hereunder.

9. INDEMNIFICATION

9.1. **Indemnification by Hammock**.

9.1.1. Hammock will indemnify MilanaPharm, its Affiliates, and its and their directors, officers, employees and agents ("MilanaPharm Indemnitees") and defend and hold each of them harmless, from and against any and all Third Party Losses to the extent resulting from, arising out of, or in connection with (a) any breach or failure to perform by a Selling Party of any of its covenants or agreements under this Agreement or (b) any breach of or inaccuracy in any of the warranties or representations made by a Selling Party in this Agreement. Notwithstanding the foregoing, Hammock will have no obligations under this Section to the extent such Losses result from, arise out of, or are connection with any matter for which MilanaPharm is obligated to indemnify the Hammock Indemnitees pursuant to Section 9.2.1 or the negligence, recklessness or willful misconduct (including non-compliance with any Applicable Laws, regulations or rules) on the part of a MilanaPharm Indemnitee.

9.1.2. Hammock will indemnify the MilanaPharm Indemnitees and defend and hold each of them harmless, from and against any and all Third Party Losses related to any personal injury or death to the extent resulting from, arising out of, or in connection with the negligence, recklessness or willful misconduct of a Selling Party with the development, manufacture, use, offer for sale, distribution, promotion, importation, exportation or marketing of a Licensed Product (other than such activities conducted by or on behalf of MilanaPharm). Notwithstanding the foregoing, Hammock will have no obligations under this Section to the extent such Losses result from, arise out of, or are connection with any matter for which MilanaPharm is obligated to indemnify the Hammock Indemnitees pursuant to Section 9.2 or the negligence, recklessness or willful misconduct (including non-compliance with any Applicable Laws, regulations or rules) on the part of a MilanaPharm Indemnitee.

9.2. **Indemnification by MilanaPharm**.

9.2.1. MilanaPharm will indemnify Hammock, its Affiliates, and its and their directors, officers, employees and agents ("Hammock Indemnitees"), and defend and hold each of them harmless, from and against any and all Losses to the extent resulting from, arising out of, or in connection with (a) any breach or failure to perform by MilanaPharm of any of its covenants or agreements under this Agreement; or (b) any breach of or inaccuracy in any of the warranties or representations made by MilanaPharm in this Agreement. Notwithstanding the foregoing, MilanaPharm will only be obligated to so indemnify, defend and hold harmless the Hammock Indemnitees to the extent that such Losses do not arise from the negligence, recklessness or willful misconduct (including non-compliance with any Applicable Laws, regulations or rules) on the part of a Hammock Indemnitee.

9.3. **Indemnification Procedures**.

9.3.1. The Party claiming indemnity under this Section 9 for itself of any of its Affiliates, or its and their directors, officers, employees or agents (the "Indemnified Party") shall give written notice to the Party from whom indemnity is being sought (the "Indemnifying Party") promptly after learning of any claim, *provided*, that the failure to provide such notice shall not affect the Indemnifying Party's obligations hereunder, except to the extent it is materially prejudiced thereby.

9.3.2. The Indemnifying Party shall have the right to assume and pursue the defense of any such claim that relates to a Third Party claim (a "Third Party Claim") upon delivery to the Indemnified Party, within thirty (30) days after the notice of such Third Party Claim has been delivered to the Indemnifying Party (an "Assumption of Defense Notice"). During the sixty (60) day period after notice of a Third Party Claim has been delivered to the Indemnifying Party, (a) the Indemnified Party shall cooperate in all reasonable respects, as the Indemnifying Party may reasonably request, in order for the Indemnifying Party to evaluate its indemnifications obligations hereunder and (b) if the Indemnifying Party has delivered an Assumption of Defense Notice with respect to a Third Party Claim, at any time during such sixty (60) day period, it may deliver to the Indemnified Party a revocation of its Assumption of Defense Notice. If the Indemnifying Party does not deliver an Assumption of Defense Notice with respect to a Third Party Claim during such thirty (30) day period, it will waive its right to control the defense of such Third Party Claim. If the Indemnifying Party delivers an Assumption of Defense Notice but does not revoke it during such sixty (60) day period, the Indemnifying Party will be deemed to irrevocably agree (absent intentional fraud on the part of the Indemnified Party) that any Losses resulting therefrom are indemnifiable Losses for which the Indemnified Party is entitled to indemnification under this Article 9. Notwithstanding the foregoing, the Indemnifying Party shall not be entitled to assume the defense of a Third Party Claim if the Indemnified Party reasonably determines, supported by written advice of counsel, that it would be inappropriate for a single counsel to represent both the Indemnifying Party and the Indemnified Party in connection with such Third Party Claim under applicable standards of legal ethics.

9.3.3. With respect to any Third Party Claim, the Indemnified Party shall permit the Indemnifying Party to control the defense and settlement thereof (subject to the cooperation obligations set forth Section 9.3.4); *provided, however*, the Indemnifying Party shall not compromise or settle any Third Party Claim without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed) unless (a) the compromise or settlement does not involve any statement, finding or admission of any fault of, breach of contract by, or violation of law by, the Indemnified Party, (b) the sole relief provided in the compromise or settlement is monetary damages that are paid in full by the Indemnifying Party and does not include any requirement that the Indemnified Party take or refrain from taking any actions other than compliance with any nondisclosure obligations related to the terms of such compromise or settlement contained in the settlement agreement, (c) the compromise or settlement includes an unconditional and irrevocable release of the Indemnified Party, (d) the settlement agreement includes a reasonable

confidentiality obligation by the third party claimant of the terms of the settlement and (e) the Indemnified Party is an express third party beneficiary of the settlement agreement, entitled to enforce such settlement agreement. Each Party shall provide the other Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the claim for which indemnity is being sought. With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense, the Indemnifying Party shall promptly inform the Indemnified Party of all material developments related thereto, including copying such Indemnified Party on all pleadings, filings and other correspondence relating thereto.

9.3.4. If the Indemnifying Party assumes the defense of any Third Party Claim, the Indemnifying Party shall consult with the Indemnified Party for the purpose of allowing the Indemnified Party to participate in such defense, but in such case (except as contemplated by the last sentence of Section 9.3.2) the legal fees and expenses of the Indemnified Party incurred as a result of such participation shall be paid by the Indemnified Party. Without limiting the generality of the foregoing, the Indemnified Party shall have a reasonable opportunity to provide input in setting the overall strategy of such defense, which the Indemnifying Party shall consider in good faith, and the Parties and shall reasonably cooperate with each other in connection with the implementation thereof.

9.3.5. No Indemnified Party may settle any claim or consent to the entry of any judgment with respect to which indemnification is being sought hereunder without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed.

10. Limitation of Liability. EXCEPT WITH RESPECT TO WILLFUL MISCONDUCT, GROSS NEGLIGENCE, A PARTY'S BREACH OF SECTION 5, 2.1.2 or 3.4, OR FOR LIABILITY ARISING FROM AMOUNTS PAID OR PAYABLE TO A THIRD PARTY PURSUANT TO A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 9, TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, IN NO EVENT WILL EITHER PARTY OR ITS AFFILIATES OR ITS OR THEIR OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER THIS AGREEMENT UNDER ANY LEGAL THEORY (INCLUDING BUT NOT LIMITED TO CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR WARRANTY OF ANY KIND) FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, SPECIAL, OR PUNITIVE DAMAGES (INCLUDING LOST PROFITS) ARISING FROM OR RELATED TO THIS AGREEMENT, EVEN IF SUCH PARTY KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF, OR COULD REASONABLY HAVE PREVENTED, SUCH DAMAGES.

11. INSURANCE

11.1. **Hammock Insurance**. Hammock shall maintain, at its own cost, commencing upon the commencement of any Clinical Trials and continuing thereafter continuously for a period of three (3) years after any expiration of termination of this Agreement, a program of insurance against liability (including Commercial General Liability Insurance policy or policies (including coverage for Product Liability, Contractual Liability, Bodily Injury, Property Damage and Personal Injury)

and other risks associated with its activities and obligations under this Agreement, including its Clinical Trials, the commercialization of any Licensed Products by Hammock, and its indemnification obligations hereunder, in such amounts, subject to such deductibles and on such terms as are customary for companies similar to Hammock for the activities to be conducted by them under this Agreement. Hammock shall not permit such insurance to be materially reduced (other than by payment of Losses), expired or canceled without reasonable prior written notice to the Licensors, unless outside of the control of Hammock. In all cases prompt notification to the Licensors of any reduction, cancellation or expiration of such insurance is required. Upon request Hammock shall provide Certificates of Insurance to the Licensors evidencing the coverage specified herein.

12. TERM AND TERMINATION

12.1. **Term; Expiration.** Unless earlier terminated in accordance with this Section, the term of this Agreement (the "Term") shall commence as of the Effective Date and remain in force until it expires as follows: (a) on a Licensed Product-by-Licensed Product and country-by-country basis, this Agreement shall expire on the date of expiration of the Royalty Term with respect to such Licensed Product in such country; and (b) this Agreement shall expire in its entirety upon the expiration of all applicable Royalty Terms under this Agreement with respect to all Licensed Products in all countries. Upon expiration of the Term with respect to any Licensed Product in a country pursuant to this Section 12.1, Hammock shall have an exclusive, fully paid-up, royalty-free, perpetual, non-terminable and irrevocable right and license, with the right to grant sublicenses, under the Licensed Intellectual Property, to research, develop, make, have made, use, offer for sale, sell, import and commercialize such Licensed Product in such country in the Field.

12.2. **Termination for Breach.** Subject to the other terms of this Agreement, this Agreement and the rights granted herein may be terminated, on a Licensed Product-by-Licensed Product basis, by either Party for the material breach by the other Party to this Agreement, provided that the breaching Party has not cured such breach within sixty (60) days (for all breaches except for breaches of payment obligations for which the cure period shall be thirty (30) days) after the date of written notice to the breaching Party, which notice shall describe such breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement pursuant to this Section (except with respect to a breach of a payment obligation); provided, further, that (a) a material breach shall be deemed to have occurred only in the event a Party materially breaches or defaults in the performance of its obligations hereunder, (b) such Party has failed to cure such breach within such sixty (60-) or thirty (30)-day period, as applicable, and (c) the other Party's termination right shall be limited to a termination of this Agreement with respect to the applicable Licensed Product and, with respect to termination by Licensors, only in the country(ies) materially and adversely impacted by such material breach. Notwithstanding the foregoing, Hammock may elect to immediately terminate this Agreement in the event MilanaPharm fails to comply with and maintain the TriLogic-MilanaPharm Agreement in full force and effect in a manner that adversely affects Hammock.

12.3. **Voluntary Termination**. Hammock may terminate this Agreement at any time upon thirty (30) days' written notice to MilanaPharm.

12.4. **Termination for Bankruptcy**. If either of Hammock of a Licensor files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within ninety (90) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

12.5. **Discontinuation of Sales**. Hammock shall promptly notify MilanaPharm in the event that Hammock, its Affiliates and Sublicensees, after having launched a Licensed Product in any country, elect to discontinue sale of such Licensed Product in such country indefinitely. In such case, MilanaPharm may terminate the license granted to Hammock under Section 2.1.1 of this Agreement solely with respect to such Licensed Product in such country forthwith by giving notice in writing to Hammock within forty-five (45) days of having first been notified in writing of such discontinuance. If Hammock and its Affiliates and Sublicensee after having launched a Licensed Product in any country discontinues all commercially reasonable marketing efforts with the intent to sell, and all sale of, the Licensed Product in such country for a period of nine (9) months or more for reasons unrelated to causes beyond the reasonable control of such affected Selling Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, factory shutdowns, failure of public utilities or common carriers, act of God, regulatory or safety issues, omission or delay in acting by any governmental authority or a Licensor, and if Hammock subsequently fails to resume all commercially reasonable marketing efforts with the intent to sell, and all material sales of, such Licensed Product in such country within sixty (60) days of having been notified in writing of such failure by MilanaPharm, then MilanaPharm may immediately terminate the license granted to Hammock under Section 2.1.1 of this Agreement solely with respect to such Licensed Product in such country forthwith by giving notice in writing to Hammock. For the purpose of this Section 12.5, sales of minimal, commercially insignificant quantities of Licensed Product in a country shall be deemed to constitute a discontinuation of sales in such country and shall also not qualify for a resumption of material sales.

12.6. **Effects of Expiration or Termination**.

12.6.1. **License upon Expiration**. Upon the expiration, but not earlier termination, of this Agreement, the licenses granted to Hammock in Section 2.1.1 shall automatically convert to the license set forth in Section 12.1.

12.6.2. **Termination of Licenses**. Upon any termination of this Agreement for any reason other than by Hammock pursuant to Section 12.2 or 12.4, (i) as of the effective date of such termination, all licenses granted by Licensors to Hammock under this Agreement shall terminate automatically, (ii) each Party shall return all Confidential Information of the other Party as required by Section 5, and (iii) the licenses granted in Section 3.4 shall survive, and the payment provisions surviving pursuant to Section 12.8 shall survive, with MilanaPharm's surviving payment obligations pursuant to Section 4.7.

12.6.3. **Termination by Hammock Pursuant to Section 12.2 or 12.4**. In the event Hammock terminates this Agreement pursuant to Section 12.2 or 12.4, then all rights and obligations of the Parties under this Agreement (other than those that expressly survive under Section 12.8) shall terminate, except that the licenses granted in Section 2.1.1 shall survive, and the payment provisions surviving pursuant to Section 12.8 shall survive, with Hammock's surviving payment obligations reduced by 50%.

12.6.4. **Survival of Sublicenses**. Notwithstanding the foregoing other than Section 12.5, no termination of this Agreement shall be construed as a termination of any sublicense of any Sublicensee hereunder, and thereafter each such Sublicensee shall be considered a direct licensee of Licensors, provided that (a) a true, correct and complete copy of such surviving sublicense agreement is provided to MilanaPharm within ten (10) business days of the termination of this Agreement, (b) Hammock has first represented and warranted to Licensors that, to Hammock's actual knowledge, as of the effective date of such termination, such Sublicensee is then in full compliance with all terms and conditions of its sublicense, (c) all accrued payment obligations to MilanaPharm have been paid, and (d) such Sublicensee agrees in writing to assume all applicable obligations of Hammock under this Agreement, including, without limitation, the obligation to pay the royalties set forth in Section 4.3.1 directly to MilanaPharm.

12.7. **Remedie**s. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Section 12 are in addition to any other relief and remedies available to either Party under this Agreement and at law.

12.8. **Surviving Provisions**. Notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in Sections 5 (Confidentiality), 8 (Representations and Warranties), 9 (Indemnification), 10 (Limitation of Liability), 12.6 (Effects of Expiration or Termination), 12.7 (Remedies), 12.8 (Surviving Provisions) and 13 (Miscellaneous), as well as any rights or obligations otherwise accrued hereunder (including any accrued payment obligations), shall survive the expiration or termination of this Agreement. For the avoidance of doubt, in the event notice of termination of this Agreement is given prior to achievement of the milestone set forth in Section 4.2, Hammock shall not be obligated to make any payment to MilanaPharm pursuant Section 4.2, except as set forth in Section 12.6.3. Termination shall not relieve any Party from any liability which has accrued prior to such termination.

13. MISCELLANEOUS

13.1. **Jurisdiction; Venue; Waiver of Jury Trial**. The sole jurisdiction, venue and dispute resolution procedure for all disputes, controversies or claims (whether in contract, tort or otherwise) arising out of, relating to or otherwise by virtue of, this Agreement, breach of this Agreement or the transactions contemplated by this Agreement shall be the United States District Court for the State of Delaware or, if such court does not have subject matter jurisdiction, in the state courts of the State of Delaware, and the parties to this Agreement hereby consent to the jurisdiction of such courts and waive any objection to the venue of such proceeding. Each of the Parties agrees that process may be served upon it in the manner specified in Section 13.3 and irrevocably waives and

covenants not to assert or plead any objection which it might otherwise have to such jurisdiction, or to such manner of service of process.

13.2. **Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof, unless the invalid or unenforceable provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid or unenforceable provision. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.3. **Notices**. Any notice required or permitted to be given by this Agreement shall be in writing and shall be (a) delivered by hand or by overnight courier with tracking capabilities, (b) mailed postage prepaid by first class, registered, or certified mail, or (c) delivered by electronic mail or facsimile with electronic delivery conformation, in each case, addressed as set forth below unless changed by notice so given:

If to Hammock:

Hammock Pharmaceuticals, Inc.
16700 Hammock Creek Pl.
Charlotte, NC 28278
Attention: William R. Maichle
E-mail: wmaichle@hammockpharma.com

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Robert M. Crawford
Facsimile: (617) 321-4432
E-mail: rcrawford@goodwinlaw.com

If to Licensors:

MilanaPharm LLC
4 Peachwood Drive
Tallassee, AL 36078
Attention: Jim Harwick
E-mail: jharwick@milanapharm.com

with a copy (which shall not constitute notice) to:

Sirote & Permutt, P.C.
2311 Highland Avenue South
Birmingham, Alabama 35205
Attention: Peter J. Hardin
Facsimile: 205-212-3805
E-mail: phardin@sirote.com

Any such notice shall be deemed given on the date received. A Party may add, delete, or change the person or address to which notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 13.3.

13.4. **Assignment**. Neither Party may, without the consent of the other Party, assign or transfer any of its rights and obligations hereunder (other than the rights granted to Licensors under Section 3.4); provided that no such consent is required for such assignment or transfer by a Party (a) to an Affiliate of such Party or (b) to a successor-in-interest by reason of merger or consolidation or sale of all or substantially all of the assets of such Party; provided further that, with respect to an assignment or transfer by such Party in accordance with the prior provisos, (i) with respect to an assignment to a successor-in-interest, such assignment includes all rights and obligations under this Agreement, (ii) such successor-in-interest or Affiliate shall have agreed as of such assignment or transfer to be bound by the terms of this Agreement in a writing provided to the other Party, and (iii) where this Agreement is assigned or transferred to an Affiliate or successor-in-interest, such assigning Party remains responsible for the performance of this Agreement and such assigning Party shall guarantee the performance of its obligations hereunder by such assignee. Notwithstanding the foregoing, neither Licensor may assign or transfer any of its rights or obligations under Section 3.4 without the prior written consent of Hammock, such consent not to be unreasonably withheld, conditioned or delayed. In the event Hammock does not provide such consent, then all rights under Section 3.4 shall terminate. Subject to the foregoing, this Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assigns. Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning, non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

13.5. **Waivers and Modifications**. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release, or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by both Parties.

13.6. **GOVERNING LAW**. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE, IRRESPECTIVE OF THE CHOICE OF LAWS PRINCIPLES OF THE STATE OF DELAWARE, AS TO ALL MATTERS, INCLUDING MATTERS OF VALIDITY, CONSTRUCTION, EFFECT, ENFORCEABILITY, PERFORMANCE AND REMEDIES.

13.7. **Relationship of the Parties**. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute any Licensor and Hammock as partners, agents, or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement, or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder.

13.8. **Entire Agreement**. This Agreement and the attached exhibits constitutes the entire agreement between the Parties as to the subject matter of this Agreement and, as of the Effective Date, supersedes and merges all prior and contemporaneous negotiations, representations, agreements, and understandings regarding the same.

13.9. **Counterparts**. This Agreement may be executed in counterparts (whether delivered by facsimile or otherwise) with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument.

13.10. **Interpretation**.

13.10.1. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel, and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

13.10.2. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms. The word "will" shall be construed to have the same meaning and effect as the word "shall." The word "any" shall mean "any and all" unless otherwise clearly indicated by context. The word "including" will be construed as "including without limitation." The word "or" is disjunctive but not necessarily exclusive.

13.10.3. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument, or other document herein shall be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein or therein), (b) any reference to any Applicable Laws herein shall be construed as referring to such Applicable Laws as from time to time enacted, repealed, or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, and (d) all references herein to Articles, Sections, or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, and Exhibits of this Agreement.

13.10.4. Headings and captions are for convenience only and are not be used in the interpretation of this Agreement.

13.11. **Section 365(n)**.

13.11.1. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined in Section 101 of such Code. Each Party, as licensee, may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, if a Party elects to retain its rights as a licensee under such Code, such Party shall be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology shall be delivered to the licensee Party not later than:

(i) the commencement of bankruptcy proceedings against the licensor, upon written request, unless the licensor elects to perform its obligations under the Agreement, or

(ii) if not delivered under Section 13.11.1(i), upon the rejection of this Agreement by or on behalf of the licensor, upon written request.

13.11.2. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

[*Signature page follows*.]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the Effective Date.

HAMMOCK PHARMACEUTICALS, INC.

By:/s/ WilliamR. Maichle
Name: William R. Maichle
Title: President

MILANAPHARM LLC

By: /s/ James A.H. Hareick
Name: James A.H. Hareick
Title: President

TRILOGIC PHARMA, LLC

By: /s/ James A.H. Hareick
Name: James A.H. Hareick
Title: President

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

APPENDIX A

LICENSED PATENTS

United States Patent No. 8,691,278 Issued: April 8, 2014	Self Solidifying Bioerodible Barrier Implant
United States Patent No. 8,501,230 B2 Issued: August 6, 2013	Self Solidifying Bioerodible Barrier Implant
China Patent No. 101557802 B Issued: Oct 30, 2013	Self Solidifying Bioerodible Barrier Implant
European Patent No. 2 219 608 B1 Issued: Mar 19, 2014	Self Solidifying Bioerodible Barrier Implant
United States Provisional Patent Application Serial No. 62/194,518 Filed: Jul 20, 2015	Topical Formulations and Treatments

Exhibit 10.10(b)

First Amendment to License Agreement

This First Amendment to License Agreement ("Amendment") is effective as of December 5, 2018 (the "First Amendment Date") and is made by and among Daré Bioscience, Inc., a Delaware corporation ("Daré"), and TriLogic Pharma, LLC, a Delaware limited liability company ("TriLogic"), and MilanaPharm LLC, a Delaware limited liability company ("MilanaPharm," and individually and collectively with Trilogic each a "Licensor" and together "Licensors"). Licensors and Daré are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

BACKGROUND

A. Licensors and Hammock Pharmaceuticals, Inc., a Delaware corporation ("Hammock"), are parties to that certain Exclusive License Agreement effective as of January 9, 2017 ("Original Agreement") pursuant to which Licensors granted to Hammock an exclusive license (or sublicense as the case may be consistent therewith) under the Licensed Patents and Licensed Know-How.

B. Contemporaneously herewith, Hammock and Daré have entered into that certain Assignment Agreement pursuant to which Hammock assigned to Daré and Daré assumed all of Hammock's rights, duties and obligations under the Original Agreement.

C. Licensors hereby consent to such assignment to and assumption by Daré of the Original Agreement, and the Parties wish to amend the Original Agreement pursuant to the terms of this Amendment.

D. Capitalized terms used but not defined in this Amendment have the meanings ascribed to them in the Original Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. Amendments. The Original Agreement is amended as follows, with such amendments effective as of the First Amendment Date:

1.1. References to Hammock. All references in the Original Agreement to Hammock shall hereafter refer to Daré Bioscience, Inc., and notices to Daré shall be sent to

3655 Nobel Drive, Suite 260, San Diego, California 92122 to the attention of its Chief Executive Officer.

1.2. Milestone Payments. The following provision shall be added to the Original Agreement as a new Section 4.2.1(vii) (and the foregoing subsection (vi) of the Original Agreement shall be amended to include a semi-colon and the word "and" to accommodate this addition):

(vii) Upon the achievement of cumulative worldwide Net Sales of Licensed Products of at least Fifty Million Dollars ($50,000,000): a onetime payment of One Million Dollars ($1,000,000).

1.3. Royalties. Section 4.3.1 of the Original Agreement is deleted in its entirety and replaced with the following:

4.3.1. **Royalty Rates**. Subject to the terms and conditions set forth in this Agreement, including, the terms of Sections 4.3.2, 4.3.3, 4.3.4, and 4.3.5, Daré will pay to MilanaPharm a royalty equal to a percentage of Annual Net Sales of each Licensed Product during the Royalty Term, which percentage is tiered in accordance with the following table, and where "**Annual Net Sales**" means total, worldwide Net Sales aggregated during any given calendar year (or portion thereof with respect to the calendar year in which the Effective Date occurs, and with respect to the calendar year during which this Agreement terminates or expires):

Percentage of Annual Net Sales	**Annual Net Sales**
[***]%	< $[***] million
[***]%	Portion of Annual Net Sales equal to or greater than $[***] million but less than $[***] million
[***]%	Portion of Annual Net Sales equal to or greater than $[***] million but less than $[***] million
[***]%	Portion of Annual Net Sales equal to or greater than $[***] million but less than $[***] million
[***]%	Portion of Annual Net Sales that is $[***] million or greater

Royalties shall be paid under this Section 4.3.1, on a country-by-country and Licensed Product-by-Licensed Product basis, on Net Sales of each Licensed Product made from the First Commercial Sale of such Licensed Product in each country during the Royalty Term applicable to such Licensed Product.

1.4. Third Party Offset. Section 4.3.4(ii) of the Original Agreement is deleted in its entirety and replaced with the following:

(ii) (a) In the event that Daré reasonably determines that rights to Patent Rights, Know-How or other intellectual property owned or controlled by a Third Party are required to exercise the licenses granted to Daré hereunder, Daré shall have the right to negotiate and acquire such rights through a license or otherwise and to deduct from the then-current payments due to MilanaPharm the amounts paid (including milestone payments, royalties or other license fees) by Daré to such Third Party.

(b) In the event that Daré reasonably determines that rights to Patent Rights, Know-How or other intellectual property owned or controlled by a Third Party are strategically important or could add value to a Licensed Product in a manner expected to materially generate or increase sales, the parties shall consult with each other with respect to such Third Party Patent Rights, Know-How or other intellectual property, and Daré shall have the right to negotiate and acquire such rights through a license or otherwise, and, upon MilanaPharm's prior consent, which it will not unreasonably withhold, condition or delay, to thereafter deduct the amounts paid (including milestone payments, royalties or other license fees) by Daré to such Third Party from the then-current payments due to MilanaPharm, subject to Section 4.3.4(ii)(c).

(c) If Daré acquires any rights described in Section 4.3.4(ii)(a) or Section 4.3.4(ii)(b), in no event shall the amounts due to MilanaPharm from Daré in any Calendar Quarter be reduced in the aggregate by more than [***] percent ([***]%); provided further that in no event shall the amounts due to MilanaPharm from Daré in any Calendar Quarter be reduced for any reason in the aggregate by more than [***] percent ([***]%). Any amount that Daré is entitled to deduct that is reduced by the foregoing limitation on the deduction, or is otherwise not deducted in a particular Calendar Quarter (for example, if the amount due to MilanaPharm is less than the amount due to such Third Party during such Calendar Quarter), such amount that was not deducted shall be carried forward for up to [***] ([***]) Calendar Quarters, and Daré may deduct such remaining and unexpired amount from subsequent amounts due to MilanaPharm until the full amount that Daré was entitled to deduct is deducted. Each Licensor shall cooperate with Daré to acquire such rights at its reasonable request and expense.

1.5. Discontinuation of Sales. Section 12.5 of the Original Agreement is deleted in its entirety and replaced with the following:

12.5. **Discontinuation of Sales**.

12.5.1 Daré shall promptly notify MilanaPharm in the event that Daré, its Affiliates and/or Sublicensees, as applicable, after having launched a Licensed Product in any country, elects to discontinue the sale of such Licensed Product in such country. In such case, MilanaPharm may terminate the license granted to Daré under Section 2.1.1 of this Agreement solely with respect to such Licensed Product in such country forthwith by giving notice in writing to Daré within sixty (60) days of having first been notified in writing of such discontinuance.

12.5.2 If Daré and its Affiliates and Sublicensee after having launched a Licensed Product in any country discontinues all commercially reasonable marketing efforts to sell, and discontinues all sales of, the Licensed Product in such country for a period of nine (9) months or more for reasons unrelated to Force Majeure (where "**Force Majeure**" means any causes beyond the reasonable control of such affected Selling Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, factory shutdowns, failure of public utilities or common carriers, act of God, regulatory or safety issues, omission or delay in acting by any governmental authority or a licensor), and if Daré, its Affiliates and/or Sublicensee subsequently fails to resume commercially reasonable marketing efforts with the intent to sell, such Licensed Product in such country within one hundred twenty (120) days of having been notified in writing of such failure by MilanaPharm, then the Parties shall meet in person to discuss the reasons for such discontinuation and failure to resume.

12.5.3 If, during such meeting, Daré reasonably demonstrates that the discontinuation and failure to resume is a strategic effort designed to increase sales of the Licensed Product in such country at a later time (and nonlimiting examples of strategic reasons include training and implementing a new distributor, re-branding and/or re-launching the Licensed Product, etc.) ("**Strategic Justification**"), then MilanaPharm shall allow Daré the opportunity to recommence sales efforts within a reasonable period of time as the Parties may agree, but not to exceed one hundred twenty (120) days from such meeting.

12.5.4 If Daré does not reasonably demonstrate a Strategic Justification during such meeting, then MilanaPharm may terminate the license granted to Daré under Section 2.1.1 of this Agreement solely with respect to such Licensed Product in such country forthwith by giving ninety (90) notice in writing to Daré.

For the purpose of this Section 12.5, sales of minimal, commercially insignificant quantities of Licensed Product in a country shall be deemed to constitute a discontinuation of sales in such country and shall also not qualify for a resumption of material sales.

1.6. Additional Milestone Payment. Section 4.2.2 of the Original Agreement is deleted in its entirety and replaced with the following:

4.2.2 **Additional Milestone Payment**. Subject to the terms and conditions set forth in this Agreement, (i) on the First Amendment Date, Daré shall pay to MilanaPharm a payment of Twenty-Five Thousand Dollars ($25,000); and (ii) within fifteen (15) days of the first to occur of (a) the first (1st) anniversary of the First Amendment Date or (b) the closing of an equity financing with a third party by Daré in which aggregate proceeds of at least Ten Million Dollars ($10,000,000) are raised (such date, the "Deferred Payment Trigger Date"), Daré shall pay MilanaPharm a fee of Two Hundred Thousand Dollars ($200,000) (the "Deferred Fee"). The Deferred Fee may be paid either (a) in cash or (b) by delivery of shares of Daré Common Stock, with such choice being made in the sole discretion of Daré. In the event that Daré elects to pay the Deferred Fee in shares of Daré Common Stock, the number of shares of Daré Common Stock shall be determined by dividing $200,000 by the average closing price of Daré common stock for the five (5) trading day period immediately preceding the Deferred Payment Trigger Date. For the purposes of the Deferred Fee, "Daré Common Stock" means shares of common stock, $0.0001 par value per share, of Daré that have been registered on a Form S-1 or Form S-3 and are eligible for trading on the NASDAQ and that when issued are duly authorized, validly issued, fully paid, and non-assessable, not subject to any pre-emptive rights, and freely tradeable by MilanaPharm on the NASDAQ upon delivery to MilanaPharm. Any failure to pay the milestone payment set forth herein when due shall constitute a breach of a payment obligation entitling MilanaPharm to proceed to terminate this Agreement in its entirety for breach pursuant to the terms of Section 12.2 of the Agreement.

2. Miscellaneous. This Amendment shall be effective from the First Amendment Date and in full force and effect until the expiration or termination of Original Agreement. Except as expressly provided in this Amendment, the Original Agreement remain unmodified and in full force and effect.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be signed in duplicate by their duly authorized representatives.

Daré Bioscience, Inc.

By: /s/Lisa Walters-Hoffert

Print Name: Lisa Walters-Hoffert

Title: Chief Financial Officer

Date: 12/05/2018

Trilogic Pharma, LLC

By: /s/ James Harwick

Print Name: James Harwick

Title: President/CEO

Date: 12/5/2018

MilanaPharm LLC

By: /s/ James Harwick

Print Name: James Harwick

Title: President/CEO

Date: 12/5/18

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	**Jurisdiction of Organization**
Daré Bioscience Operations, Inc.	Delaware
Daré Bioscience Australia Pty Ltd	Australia
Pear Tree Pharmaceuticals, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

As independent registered public accountants, we hereby consent to the incorporation by reference in Registration Statement on Form S-3 (Nos. 333-206396, 333-227019, 333-227022) of our report dated April 1, 2019, with respect to the financial statements of **Daré Bioscience, Inc. and Subsidiaries** as of and for each of the years in the two year period ended December 31, 2018 (which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern), included in this annual report on Form 10-K of **Daré Bioscience, Inc. and Subsidiaries** for the years ended December 31, 2018 and 2017.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
April 1, 2019

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Sabrina Martucci Johnson, certify that:

1. I have reviewed this annual report on Form 10-K of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: April 1, 2019

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Lisa Walters-Hoffert, certify that:

1. I have reviewed this annual report on Form 10-K of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: April 1, 2019

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

Exhibit 32.1

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

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Daré Bioscience, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2018 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 1, 2019

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

Exhibit 32.2

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

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Daré Bioscience, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2018 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 1, 2019

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