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, 2019
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, 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	Trading Symbol(s)	**Name of each exchange on which registered**
Common Stock, Par Value $0.0001 Per Share	**DARE**	**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 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	o

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 the last business day of the registrant's most recently completed second fiscal quarter (June 28, 2019), was approximately $12,232,000 based on the closing price as reported on the Nasdaq Capital Market. This excludes shares of common stock held by affiliates on such date. 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 26, 2020, there were 24,690,404 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 2020 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, 2019
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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, in particular "Item 7. 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, including as a result of the effects of the COVID-19 pandemic;*
- *Inability to successfully attract partners and enter into collaborations on acceptable terms;*
- *A decision by Bayer HealthCare LLC to discontinue its commercial interest in Ovaprene and/or to terminate our license agreement;*
- *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, including as a result of matters beyond our control such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic;*
- *A change in the FDA Center assigned primary oversight responsibility for our combination product candidates;*
- *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 nonclinical studies and clinical trials of our product candidates;*

- *Dependence on third parties to supply and manufacture clinical trial materials and, if any of our candidates are approved, commercial product, including components of our products as well as the finished product, in accordance with current good manufacturing practices and in the quantities needed;*
- *Interruptions in, or the complete shutdown of, the operations of third parties on which we rely, including clinical sites, manufacturers, suppliers, and other vendors, from matters beyond their control, such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic, and our lack of recourse against such third parties if their inability to perform is excused under the terms of our agreements with such parties;*
- *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;*
- *Uncertainty as to whether health insurance plans will cover our product candidates even if we successfully develop and obtain regulatory approval for them;*
- *Unfavorable or inadequate reimbursement rates for our product candidates set by the United States government and other third-party payers even if they become covered products under health insurance plans;*
- *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;*
- *Failure to maintain the listing of the Company's common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *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 acceleration of innovative products for women’s health. We are driven by a mission to identify, acquire and develop a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, fertility, and sexual and vaginal health.

Our Strategy

Our business strategy is to in-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, and then out-license these products to companies with sales and distribution capabilities in women's health to leverage their commercial capabilities.

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 product candidates, including clinical-stage candidates, often with published human data. Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through mid- and late stages of clinical development or approval. Our global commercialization and development strategy involves partnering with pharmaceutical companies and regional distributors with established marketing and sales capabilities in women's health, including through co-development and promotion agreements, once we have advanced a candidate through mid- to late-stage clinical development.

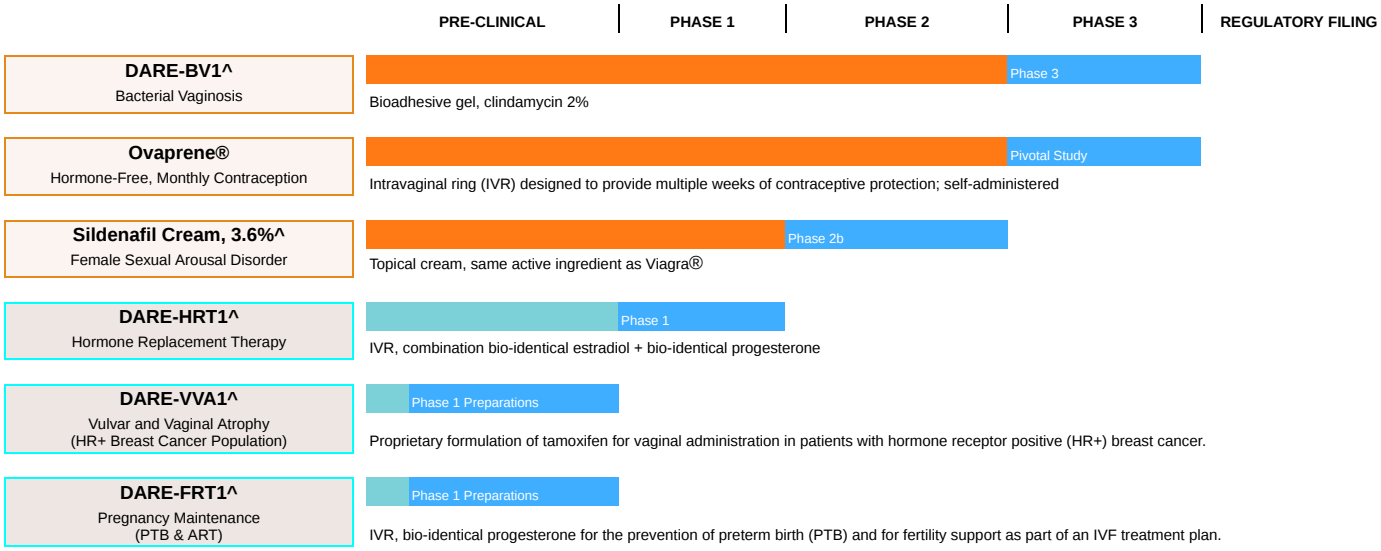
Our Clinical-Stage Product Candidates and Programs

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 Exemption applications, 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 in the U.S.

(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.

Our initial focus is in the areas of contraception, vaginal health, sexual health and fertility, and we have acquired, or acquired rights to, candidates in these areas with promising early clinical and/or pre-clinical testing data developed by third parties. We believe the product candidates currently in our portfolio offer innovative therapeutic approaches that may provide meaningful benefits over current treatment options. Our portfolio includes three product candidates in advanced stages of clinical development and three candidates that we believe are Phase-1 ready. The following graphic provides a snapshot of these candidates, including their targeted indications and our current expectations for their respective stages of development in 2020:



^ We intend to utilize the FDA's 505(b)(2) pathway for this candidate.

DARE-BV1

DARE-BV1 is a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% that we are developing as a first-line, single-administration treatment for bacterial vaginosis, or BV. Clindamycin is an antibiotic with FDA approval to treat certain bacterial infections, including BV. DARE-BV1 is designed to transition from a viscous liquid to a bioadhesive gel at body temperature following vaginal self-administration, and to release the active ingredient over a period of up to seven days. The bioadhesive properties of DARE-BV1 are expected to reduce leakage and prolong the duration of exposure of clindamycin relative to currently marketed creams, potentially improving the rate of clinical effectiveness compared to existing FDA-approved therapies, including cream formulations of clindamycin. We plan to leverage existing safety and efficacy data on clindamycin to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-BV1 for BV in the U.S.

According to the Centers for Disease Control and Prevention, or the CDC, BV is the most common vaginal condition in women ages 15-44. 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. Current FDA-approved therapies have clinical cure rates (based on the Amsel criteria) ranging from 37-68%.

Prior to our involvement, DARE-BV1 was evaluated in an investigator-initiated proof-of-concept study that enrolled 30 women, ages 18 to 50, to assess its efficacy in treating BV after a single administration. The study's primary efficacy endpoint was clinical cure based on the Amsel criteria at the test-of-cure evaluation visit, or Visit 2, which was approximately 7 to 14 days after administration of DARE-BV1. Of the 28 evaluable subjects, 24, or 86%, achieved clinical cure at Visit 2. The women were asked to return to the clinic for a third visit, or Visit 3, approximately 21 to 30 days following administration of DARE-BV1 to evaluate continued efficacy of treatment. Of the 24 subjects who completed Visit 2 and were deemed clinically cured, 23, or 96%, remained clinically cured at Visit 3. There were no reports of adverse reactions, including local reactions to DARE-BV1. We believe DARE-BV1's unique adhesion properties and release profile led to the encouraging cure rates in the pilot study.

In August 2019, the FDA granted DARE-BV1 Qualified Infectious Disease Product (QIDP) designation for the treatment of BV in women. QIPD designation is available under Title VIII of the FDA Safety and Innovation Act, titled General Antibiotic Incentive Now (GAIN), which creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The primary incentive is a five-year exclusivity extension added to any exclusivity for which a QIDP qualifies upon FDA approval. Additionally, DARE-BV1's QIDP designation makes it eligible for Fast Track designation and Priority Review. In March 2020, we announced that we received Fast Track designation from the FDA for DARE-BV1 for the treatment of BV. The designation offers the opportunity for more frequent interactions with the FDA to discuss DARE-BV1's development plan and ensure collection of appropriate data needed. The Fast Track program is intended to facilitate development and expedite review of a Fast Track drug so that an approved product can reach the market expeditiously.

We are currently working on regulatory and start-up activities that are necessary to commence a Phase 3 multicenter, randomized, double-blind, placebo-controlled study of DARE-BV1 for the treatment of BV, or the DARE-BV1-001 study, and expect to initiate the study in the second half of 2020. We plan to enroll approximately 220 postmenarchal women, ages 12 and above, at approximately 40 sites in the United States. The primary efficacy endpoint of the study will be clinical cure at the evaluation visit to occur 21 to 30 days after enrollment in the study, or the Day 21-30 visit, with clinical cure defined as meeting three criteria (derived from the Amsel criteria): resolution of abnormal vaginal discharge associated with BV as confirmed by the investigator; a negative 10% potassium hydroxide (KOH) "whiff test"; and the presence of clue cells at less than 20% of total epithelial cells in a saline wet mount. If the study's initiation and rate of subject enrollment occur as we currently expect, then we anticipate having topline data from this study before year end 2020. Based on our pre-investigational new drug (PIND) communications with the FDA, in parallel with the DARE-BV1-001 clinical study and to support the new drug application, or NDA, for DARE-BV1, we will conduct nonclinical studies of certain excipients in DARE-BV1 and the clinical formulation of DARE-BV1, including reproductive toxicology studies. If the DARE-BV1-001 clinical study and the nonclinical studies are completed as anticipated and if their outcomes are successful, then we expect to be in a position to file an NDA with the FDA in early 2021. We anticipate that the aggregate costs of the DARE-BV1-001 clinical study, planned nonclinical studies, manufacturing activities for the program through filing of the NDA, and including such NDA filing, will be approximately $10.0 million. Our anticipated timelines and aggregate costs for the development of our product candidates could be delayed and could increase as a result of the COVID-19 pandemic. See "ITEM 1A.–Risk Factors–Risks Related to Clinical Development, Manufacturing and Commercialization–Delays in the commencement or completion of clinical testing of our current and any future product candidates we may seek to develop may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable," below.

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, hormone-free method of contraception that does not require intervention at the time of intercourse.

Ovaprene is a novel, hormone-free intravaginal ring, or IVR, for pregnancy prevention designed to be worn conveniently over multiple weeks (one menstrual cycle) and with the potential to achieve “typical use” contraceptive efficacy (which is the expected rate of pregnancy protection when the product is used widely under everyday circumstances) comparable to current non-implanted hormonal contraceptive methods (pills, patches and vaginal rings), which is approximately 91% typical use efficacy. Ovaprene features a proprietary knitted polymer barrier to physically block sperm from entering the cervical canal within a silicone-reinforced ring that releases two non-hormonal agents, ascorbic acid and ferrous gluconate, that impede sperm motility. Unlike current FDA-approved contraceptive IVRs, Ovaprene does not contain hormones, but, consistent with those IVRs, including Merck’s NuvaRing®, Ovaprene is designed to be a “one size fits most” monthly, self-administered product. If approved, Ovaprene could be the first hormone-free, monthly contraceptive option for women.

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

In a postcoital test, or PCT, pilot clinical study conducted by the previous sponsor 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.

In November 2019, we announced positive topline results of our PCT clinical trial of Ovaprene. We designed the PCT clinical trial to assess general safety and effectiveness in preventing progressively motile sperm from reaching the cervical canal following intercourse and acceptability of the product to the patient. The study evaluated 23 women over the course of five menstrual cycles, with each woman assessed over approximately 21 visits. Each woman's cervical mucus was measured at several points during the study, including a baseline measurement at menstrual cycle 1 that excluded the use of any product. Subsequent cycles and visits included the use of a diaphragm during intercourse (menstrual cycle 2) and Ovaprene (menstrual cycles 3, 4 and 5). The primary endpoint of the study was to evaluate changes from baseline in PCT results due to device use, as represented by the proportion of women and cycles with an average of fewer than five progressively motile sperm (PMS) per high power field (HPF) in midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.

Our PCT clinical trial met its primary endpoint: Ovaprene prevented the requisite number of sperm from reaching the cervix across all women and all cycles evaluated. Specifically, in 100% of women and cycles, an average of less than five PMS per HPF were present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place. To calculate the average number of PMS, PMS were counted across each of nine HPFs and averaged. Women enrolled in the study who completed at least one Ovaprene PCT (N=26) had a mean of 27.21 PMS/HPF in their baseline cycle when no contraception was used, a mean of 0.22 PMS/HPF in their diaphragm cycle, which was anticipated based on published studies, and a mean of 0.48 PMS/HPF in their Ovaprene PCT cycles, with a median of zero PMS. No serious or severe adverse events were reported or observed.

PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness. Infertility research suggests that higher rates of pregnancy are associated with PMS per HPF of from greater than one to greater than 20 sperm, and less than five PMS per HPF is considered indicative of contraceptive effectiveness.

Based on the positive results of our PCT clinical trial, we currently intend to file an IDE, with the FDA in 2020, and, pending FDA review and clearance of the IDE, to initiate a pivotal clinical study of Ovaprene in the second half of 2020. We are designing that study to evaluate the safety and efficacy of Ovaprene to prevent pregnancy when used over a period of 12 months by approximately 250 women and will seek to confirm alignment with the FDA on the study's design prior to commencement. If successful, we expect the study's data to support our PMA submission to the FDA, as well as marketing approvals of Ovaprene in Europe and other countries worldwide.

We are developing Ovaprene with ADVA-Tec, Inc. and Bayer HealthCare LLC, or Bayer, as part of two strategic collaborations announced in March 2017 and January 2020, respectively. See "License Agreements" below for discussion of the terms of each collaboration.

Sildenafil Cream, 3.6%

While numerous pharmaceutical products have been developed and approved to treat erectile dysfunction in men, women continue to lack effective options for female sexual arousal disorder, or FSAD, the most analogous condition of the various types of female sexual dysfunction disorders. We are developing Sildenafil Cream, 3.6%, a proprietary cream formulation of sildenafil, the active ingredient in the male erectile dysfunction drug Viagra®, for topical administration to the vulva and vagina for treatment of FSAD. Today, there are no FDA-approved products that specifically address the symptoms or underlying pathology of FSAD. 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. for the treatment of women suffering from FSAD. If approved, Sildenafil Cream, 3.6% could be the first FDA-approved FSAD treatment option for women.

FSAD is a condition characterized primarily by a persistent or recurrent inability to attain or maintain sufficient genital arousal (an adequate lubrication-swelling response) during sexual activity, frequently resulting in distress or interpersonal difficulty. This is distinct from hypoactive sexual desire disorder (HSDD) in women, which is characterized primarily by a lack of sexual desire. As with erectile dysfunction in men, FSAD in women is associated with insufficient blood flow to the genitalia. Sildenafil Cream, 3.6% is designed to increase genital blood flow and provide improvements in the female genital arousal response, while avoiding systemic side effects observed with oral formulations of sildenafil.

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, women with FSAD, ages 21 to 60, received a single 2 g dose of Sildenafil Cream, 3.6%. Of the 35 women enrolled, 31 (15 pre-menopausal and 16 post-menopausal) completed the study. The primary objective was to evaluate the efficacy of Sildenafil Cream, 3.6% compared to placebo cream assessed by participant-reported levels of subjective cognitive sexual arousal and by physiological genital arousal response. Sildenafil Cream, 3.6% demonstrated increases in measurable blood flow to the genital tissue compared to placebo (mean change in vaginal pulse amplitude analysis) using a vaginal photoplethysmograph approximately 30 minutes post-dosing. Based on this study, it was determined that subjective cognitive sexual arousal assessments may not be concordant with genital sensations of arousal, which helped guide study design for our planned Phase 2b clinical trial.

A Phase 1, single-dose, double-blind, placebo-controlled, two-way crossover study to evaluate the feasibility of using thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women was conducted at a single center. During the thermography study, genital temperature, a surrogate for genital blood flow, was captured and recorded utilizing an infrared camera capable of detecting heat patterns from blood flow in body tissues. The study, which was designed to evaluate up to 10 subjects, achieved the study objectives based on a planned interim analysis of the first six completed subjects, and thus additional subjects were not enrolled. In this study, Sildenafil Cream, 3.6% demonstrated significantly greater increases in genital temperature compared to placebo cream and no cream. Additionally, significantly greater self-reported arousal responses were reported during Sildenafil Cream, 3.6% visits compared to placebo cream visits.

In 2019, as part of our Phase 2b clinical program for Sildenafil Cream, 3.6%, we completed a non-interventional study, or the content validity study, designed to identify and document the genital arousal symptoms that will be assessed in our Phase 2b trial, in which subjects will use Sildenafil Cream, 3.6% and placebo cream in their home setting, and to demonstrate that those symptoms are the most important and relevant to our target population and are also acceptable endpoints for the FDA. Participants who met the eligibility criteria participated in one-on-one, in-depth interviews conducted by subject matter experts in the field of clinical outcome assessments and female sexual medicine. In December 2019, we announced that, following a review of the findings of the content validity study with the FDA, alignment was reached with the FDA on the design of our Phase 2b clinical trial, including the patient reported outcome, or PRO, instruments to be used to screen eligible patients with FSAD and to measure achievement of the primary efficacy endpoints, namely improvement in localized genital sensations of arousal and reduction in the distress that women with FSAD experience. We also aligned with the FDA on several exploratory efficacy endpoints that could potentially prove to be additional measurements of efficacy in a future Phase 3 program. Further, we confirmed with the FDA that no additional nonclinical or clinical data are required before initiating the Phase 2b at-home clinical trial. The Phase 2b trial is designed to evaluate Sildenafil Cream, 3.6% compared to placebo cream over 12 weeks of dosing following both a non-drug and placebo run-in period.

We plan to initiate the Phase 2b clinical trial in 2020. In addition, we will continue to actively engage with the FDA in 2020 to help ensure that any additional required studies and activities may be completed during the course of the clinical development program to support an NDA submission.

We are developing Sildenafil Cream, 3.6% with Strategic Science & Technologies-D LLC under our license and collaboration agreement announced in February 2018. See “License Agreements” below for discussion of the terms of this collaboration.

DARE-HRT1

DARE-HRT1 is a unique IVR containing bio-identical estradiol and bio-identical progesterone that is designed to be worn over multiple weeks for sustained drug delivery for the treatment of vasomotor symptoms, or VMS, associated with menopause as part of a hormone replacement therapy regimen. 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. Unlike other vaginal ring technologies, ours 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.

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. There are currently no FDA-approved IVRs that deliver bio-identical progesterone in combination with bio-identical estradiol. As such, DARE-HRT1 has the potential to be a first-in-category product that offers monthly convenience for women. We intend to leverage the existing safety and efficacy data on the active ingredients in DARE-HRT1, estradiol and progesterone, to utilize the FDA’s 505(b)(2) pathway to obtain marketing approval of DARE-HRT1 in the U.S.

We are in the process of initiating a Phase 1 open-label, three-arm, parallel group clinical study in Australia to evaluate the pharmacokinetics, or PK, and safety of DARE-HRT1 in approximately 30 healthy, post-menopausal women. The primary objectives of the 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 by the end of 2020.

We are developing DARE-HRT1 under our license agreement with Catalent JNP, Inc. See “License Agreements” below for discussion of the terms of that agreement.

DARE-VVA1

DARE-VVA1 is a proprietary formulation of tamoxifen for vaginal administration. We are developing DARE-VVA1 as an alternative to estrogen-based therapies for the treatment of vulvar and vaginal atrophy, or VVA, in women with or at risk for hormone-receptor positive (HR+) breast cancer, including women on anti-cancer therapy, to treat the symptoms of VVA. Tamoxifen is a well-known and well-characterized selective estrogen receptor modulator, or SERM. Tamoxifen has unique properties that produce different effects in different types of tissues. In breast tissue, tamoxifen acts as an estrogen antagonist, meaning that it can inhibit estrogen's effect and hence why it may be effective in treating hormone-receptor positive (HR+) breast cancer. However, in other tissue, including vaginal tissue, tamoxifen has been reported to exert an estrogen-like response. This has the potential to have a favorable effect on vaginal cytology. VVA is an inflammation of the vaginal epithelium due to the reduction in levels of circulating estrogen, which is characterized by pain during intercourse, vaginal dryness and irritation. Commonly used therapies for VVA are estrogen-based and often contraindicated in HR+ breast cancer patients, or patients with a genetic predisposition or history of familial disease, because of the concern that estrogen use will promote recurrence of disease. Due to the prevalence of aromatase inhibitors for the treatment of HR+ breast cancer, the prevalence of VVA in post-menopausal breast cancer patients is estimated to be between 42 and 70 percent. In 2020, we plan to conduct activities that will enable us to advance DARE-VVA1 into Phase 1 clinical development during 2021. The timing and availability of additional funding will impact the timing of initiation of a Phase 1 clinical study of DARE-VVA1. We intend to leverage the existing safety and efficacy data for tamoxifen to utilize the FDA’s 505(b)(2) pathway to obtain marketing approval of DARE-VVA1 in the U.S.

DARE-FRT1

DARE-FRT1 is an IVR containing bio-identical progesterone for the prevention of preterm birth (PTB) and for fertility support as part of an in vitro fertilization, or IVF, treatment plan. DARE-FRT1 was developed from the same IVR technology platform as DARE-HRT1. In 2020, we plan to conduct activities that will enable us to advance DARE-FRT1 into Phase 1 clinical development during 2021. The timing and availability of additional funding will impact the timing of initiation of a Phase 1 clinical study of DARE-FRT1. We intend to leverage the existing safety and efficacy data for progesterone to utilize the FDA’s 505(b)(2) pathway to obtain marketing approval of DARE-FRT1 in the U.S.

Sales and Marketing

We currently have no formal internal marketing or sales infrastructure or capabilities. To commercialize our products, 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.

In January 2020, we entered into an exclusive license agreement with Bayer for the commercialization of Ovaprene in the U.S. See “License Agreements” below for discussion of the terms of this collaboration.

Manufacturing and Suppliers

We do not own or operate, nor do we currently plan to establish, manufacturing facilities for the production of our product candidates. We rely on third-party contract manufacturers, or CMOs, to provide all the material and supplies for our nonclinical and clinical studies, and, if our product candidates receive regulatory approval, we expect to rely on CMOs to produce commercial quantities of our products, as well as the raw materials, drug substances, excipients and other supplies required to produce the finished products. These arrangements allow us to maintain a smaller and more flexible infrastructure.

We have no long-term arrangements for the production or supply of our product candidates or the materials required to produce them except with respect to Ovaprene and Sildenafil Cream, 3.6%. Under our agreements with ADVA-Tec and SST, respectively, ADVA-Tec is responsible for providing all clinical trial and commercial supplies of

Ovaprene, either directly or through a CMO, and SST is responsible for providing Sildenafil Cream, 3.6% for the planned Phase 2b clinical study. For further clinical development, we plan to utilize CMOs to produce and supply Sildenafil Cream, 3.6%. As we advance our product candidates toward regulatory approval, we intend to identify, qualify and enter into long-term arrangements with CMOs for commercial production of each approved product.

We expect that our current arrangements will meet our foreseeable needs for clinical trial materials or, generally, that alternative supply sources will be readily available. However, for some key raw materials or components of our clinical-stage product candidates, including Ovaprene and Sildenafil Cream, 3.6%, alternative supply sources may not be readily available. See “ITEM 1A. Risk Factors-Risks Related to our Business-Our success relies on third-party suppliers and manufacturers of our product candidates, including multiple single source suppliers and manufacturers," below.

License Agreements

Hammock/MilanaPharm Assignment and License Agreement

In December 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. In December 2019, we entered into amendments to each of the Assignment Agreement and License Amendment.

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

License Fees. We paid MilanaPharm: (1) $25,000 in connection with the execution of the License Amendment; (2) $100,000 on December 5, 2019; and (3) $110,000 on January 31, 2020.

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, as amended.

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 Hammock: (1) $250,000 in connection with the execution of the Assignment Agreement; (2) $125,000 on December 5, 2019; and (3) $137,500 on January 31, 2020.

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 milestone payments.

ADVA-Tec License Agreement

In March 2017, we entered into a 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, 2020, this patent portfolio includes nine issued U.S. patents and two pending U.S. patent applications, and 60 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 this 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; the FDA's approval to commence a pivotal clinical trial; successful completion of such pivotal 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. The successful postcoital clinical study occurred during the fourth quarter of 2019 and we expect that we will obtain the FDA's approval

to commence a pivotal clinical study in the second half of 2020. Because future milestone payments depend upon the successful progress of our product development programs, we cannot estimate with certainty when these payments will occur.

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 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.

Bayer HealthCare LLC License Agreement

On January 10, 2020, we entered into a license agreement with Bayer regarding the further development and commercialization of Ovaprene in the U.S. We received a $1.0 million upfront payment from Bayer and Bayer will support us in development and regulatory activities by providing the equivalent of two experts to advise us in clinical, regulatory, preclinical, commercial, CMC and product supply matters. Bayer, in its sole discretion, has the right to make the license effective by paying us an additional $20.0 million, referred to as the Clinical Trial and Manufacturing Activities Fee. Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with us with regard to development.

The following is a summary of the other terms of the Bayer license agreement:

Milestone Payments Paid by Bayer. We will be entitled to receive (a) a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S. and escalating milestone payments based on annual net sales of Ovaprene during a calendar year, totaling up to $310.0 million if all such milestones, including the first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Efforts. We will be responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and we have product supply obligations. After payment of the Clinical Trial and Manufacturing Activities Fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

Term. The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of (a) the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S.; or (b) 15 years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days' notice and the agreement will automatically terminate if we do not receive the Clinical Trial and Manufacturing Activities Fee if and when due.

SST License and Collaboration Agreement

In February 2018, we entered into a license and collaboration agreement with Strategic Science and Technologies-D, LLC and Strategic Science Technologies, LLC, referred to collectively as SST, under which we received 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 existed as of the effective date of this 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 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 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 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 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 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 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 agreement without cause upon 180 days prior written notice; and (3) SST may terminate the 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.

Catalent JNP License Agreement

In April 2018, we entered into an exclusive license agreement with Catalent JNP, Inc. (formerly known as Juniper Pharmaceuticals, Inc., and which we refer to as Catalent in this report), under which Catalent granted us (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, 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 Catalent 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 us under this agreement.

The following is a summary of other terms of the Catalent license agreement:

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

Annual Maintenance Fee. We will pay an annual license maintenance fee to Catalent on each anniversary of the date of the 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 Catalent in the same calendar year but may not be carried forward to any other year. We made the first of these payments in April 2019.

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 agreement.

Royalty Payments. During the royalty term, we will pay Catalent mid-single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, we will pay Catalent a low double-digit percentage of all sublicense income we receive for the sublicense of rights under the 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 agreement.

Term. Unless earlier terminated, the term of the 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 agreement, the licenses granted thereunder will convert automatically to fully-paid irrevocable licenses. Catalent may terminate the agreement (1) upon 30 days' notice for our uncured breach of any payment obligation under the 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 agreement. We may terminate the 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 Catalent terminates the agreement for the reason described in clause (4) above or if we terminate the agreement, Catalent will have full access including the right to use and reference all product data generated during the term of the agreement that is owned by us.

Microchips Acquisition

In November 2019, we acquired Microchips Biotech, Inc., or Microchips, via a merger transaction in which a wholly owned subsidiary we formed for purposes of this transaction merged with and into Microchips, and Microchips survived as our wholly owned subsidiary. Microchips is developing a proprietary, microchip-based, implantable drug delivery system designed to store and precisely deliver numerous therapeutic doses over months and years on a schedule determined by the user and controlled via wireless remote. Microchips' lead product candidate is a pre-clinical stage contraceptive application of the technology that utilizes levonorgestrel.

At the closing of the merger, we issued an aggregate of approximately 3.0 million shares of our common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger. Such shares were in consideration of Microchips' cash and cash equivalents, less liabilities, at closing. Microchips' cash and cash equivalents at closing were approximately $5.9 million after taking into account payment of transaction-related expenses.

We agreed to pay the following contingent consideration to the former Microchips stockholders: (1) up to $46.5 million contingent upon the achievement of specified funding, product development and regulatory milestones; up to $2.3 million of which we may elect to pay in shares of our common stock, subject to approval of our stockholders to the extent necessary to comply with Nasdaq Listing Rule 5635; (2) up to $55.0 million contingent upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property we acquired in the merger; (3) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, subject to customary provisions permitting royalty reductions and offset; and (4) a percentage of sublicense revenue related to such products.

The shares issued in connection with the Microchips merger will be held in escrow for a period of eighteen months to satisfy the indemnification obligations of the Microchips stockholders under the merger agreement. We agreed to register the shares of our common stock issued at the closing as well as any shares issuable after the closing as

contingent consideration to the former Microchips stockholders for resale under the Securities Act of 1933 within 180 days of closing.

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

Under the terms of the ADVA-Tec license agreement, we are the exclusive licensee of nine granted U.S. patents and two pending U.S. patent applications, and 60 granted patents and four pending patent applications in other major markets. Two of the patents that are particularly important to the protection of Ovaprene have terms until August 2028, including patent term adjustment, and a third patent has a term until July 2027, including patent term adjustment.

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 thirteen foreign patents), along with one pending U.S. patent application that has received a Notice of Allowance and four pending worldwide patent applications, including tone that has received a Notice of Allowance. 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 Catalent 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, six issued foreign patents with patent terms until April 2024, one pending U.S. application and two pending foreign applications that if granted will have patent terms until May 2038.

We filed two provisional applications in 2019 related to DARE-HRT1. We plan to file a non-provisional application or applications related to the provisional applications in 2020.

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:

- A microchip-based, implantable drug delivery system and a contraceptive application of that technology utilizing levonorgestrel that is designed to provide user-controlled, long-acting reversible contraception;
- ORB-204 and ORB-214, 6-month and 12-month formulations of injectable etonogestrel for contraception; and
- DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

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.

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 study 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. The current Presidential administration and certain members of the U.S. Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the ACA. President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In December 2019, the Fifth Circuit Court of Appeals upheld a district court's finding that the individual mandate in the ACA is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the ACA, but not specifically related to the individual mandate or health insurance, could be severed from the rest of the ACA so as not to have the law declared invalid in its entirety. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the ACA will affect the implementation of that law and our business. We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional congressional action is taken. Additionally, in January 2013, the President signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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, 2019, we had fifteen full-time and three part-time employees, ten in research and development and eight 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 rapidly increase the number of full-time employees and their associated costs.

Company Information

We were incorporated in Delaware in December 2005. Until July 2017, our corporate name was Cerulean Pharma Inc., or Cerulean. In July 2017, Cerulean completed a business combination with Daré Bioscience Operations, Inc., at which time we changed our name to "Daré Bioscience, Inc." We and our wholly owned subsidiaries operate in one business segment.

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. 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, 2019 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.

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, 2019, our cash and cash equivalents were $4.8 million and our accumulated deficit was approximately $44.0 million. We incurred a net loss of approximately $14.3 million for the year ended December 31, 2019. We may never become profitable. We expect negative cash flows from our operations to continue for the foreseeable future. Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over the next 12 months from the date of issuance of the accompanying consolidated financial statements unless we raise additional capital or significantly curtail our operations. See also “We expect to be 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” below.

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. In addition, we may enter into collaborations, such as our license agreement with Bayer, that do not provide significant near-term or guaranteed funding, thus requiring that we continue to seek to raise additional capital to fund product development through other means. See also “-We may not receive any additional payments under our license agreement with Bayer, and Bayer may terminate the agreement at any time without cause upon limited prior notice,” below.

There can be no assurance that we can raise capital when needed or on terms favorable to us and our stockholders, particularly in light of the effects that the COVID-19 pandemic has had on the capital markets and investor sentiment, and the restrictions on travel and meetings resulting therefrom which may prohibit or limit our ability to engage with potential investors in face-to-face meetings and conferences. 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 as currently planned or at all, 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 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.

We may not receive any additional payments under our license agreement with Bayer, and Bayer may terminate the agreement at any time without cause upon limited prior notice.

In January 2020, we entered into an exclusive license agreement with Bayer for the commercialization of Ovaprene in the U.S. Under our agreement, Bayer will have no future payment obligations to us, unless, after reviewing the results of our pivotal clinical trial of Ovaprene, it elects, in its sole discretion, to make the license grant under our agreement effective. Should Bayer elect to do so, it must pay us an additional $20.0 million (the “Clinical Trial and Manufacturing Activities Fee”). If we do not successfully complete clinical development of Ovaprene in a timely manner, the license grant may never become effective, and we may not receive any additional payments from Bayer. Bayer may decide not to pay the Clinical Trial and Manufacturing Activities Fee regardless of the outcome of the pivotal clinical trial. Further, Bayer may elect to terminate the license agreement without cause at any time upon 90 days’ prior notice. If the license grant does not become effective or if Bayer terminates the agreement, our ability to complete development of and commercialize Ovaprene may be significantly impaired and it could have material adverse effect on our business and prospects in general and on our stock price.

If Bayer elects to make the license grant effective, it will obtain exclusive rights to commercialize Ovaprene in the U.S. In this case, Ovaprene's value to us will be generated through royalties on net sales and achievement of commercial milestones. If Bayer is not successful or has limited success in commercializing Ovaprene, Ovaprene’s value to us will be significantly impaired. We may realize only a small fraction of the potential value of the license agreement. Other than the upfront fee, the Clinical Trial and Manufacturing Activities Fee and a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S., Bayer’s milestone and royalty payment obligations are based on annual net sales of Ovaprene. Successful commercialization of a contraceptive product is subject to many risks and uncertainties, including factors outside of our control or Bayer’s. We may never receive the full amount of potential milestone payments under the agreement, and royalty and sublicense payments, if any, may be far less than projected. Failure to realize significant value under our license agreement with Bayer could have a material adverse effect on our business, results of operations and financial condition.

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

In 2019 and through March 26, 2020, we raised approximately $11.2 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 currently is, and may continue to 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, we currently are subject to the "baby shelf rule" because 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 on Form S-3 and has been less than $75.0 million since such time. This means that we may use our currently effective shelf registration statement to raise additional funds only to the extent 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 does not exceed one-third of the aggregate

market value of our public float, calculated in accordance with the instructions to Form S-3. As an example, as of March 26, 2020, we could not offer or sell more than approximately $1.7 million of new securities under our shelf registration statement. If our ability to offer securities under our shelf registration statement is limited, including by the baby shelf rule, 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 raise capital on a timely basis through the issuance and sale of equity securities may also be limited by Nasdaq’s stockholder approval requirement for any transaction that is not a public offering (as defined in Nasdaq listing rules). For transactions other than public offerings, Nasdaq requires stockholder approval prior to the issuance or potential issuance of common stock (or securities convertible into or exercisable for common stock) at a price per share that is less than the "Minimum Price" if the issuance (together with sales by our officers, directors and substantial shareholders (as defined in Nasdaq listing rules)) would equal 20% or more of our common stock outstanding before the issuance. Under Nasdaq rules, the "Minimum Price" means a price that is the lower of (i) the Nasdaq official closing price immediately preceding the signing of the binding agreement; or (ii) the average Nasdaq official closing price of the common stock for the five trading days immediately preceding the signing of the binding agreement. In addition, certain prior sales of securities by us may be aggregated with any offering we may propose at a price that is less than the Minimum Price and which is not considered a public offering by Nasdaq, further limiting the amount we could raise in the offering. Under Nasdaq 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.

In addition, although a public offering under Nasdaq rules is not subject to the 20% limitation described above, it may involve publicly announcing the proposed transaction before it is completed, which often has the effect of depressing a company's stock price. Accordingly, our existing investors may suffer greater dilution if we seek to raise additional capital through such a public offering of our securities.

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, we may be unable to pursue and complete the clinical trials we would like to pursue and complete, and we may be unable to commence or complete clinical trials in accordance with our current timeline expectations.

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 determinations with regard to the indications and clinical trials on which to focus our resources that result in our realization of less than the full potential value of a product candidate. 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.

See also “Delays in the commencement or completion of clinical testing of our current and any future product candidates we may seek to develop may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable” below.

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, fertility and sexual and vaginal health 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 all of the product candidates to which we hold licenses and options to license through development and regulatory approval. Executing our business strategy requires us to obtain additional capital to advance our portfolio and maintain our rights to our product candidates through clinical development and eventually to commercialization or strategic partnership, as well as to license or otherwise acquire rights to additional product candidates and to similarly advance any such future product candidates. Additional 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 development activities that we did not anticipate, or should the duration of our planned and 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 and/or regulatory 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 could 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. We face significant competition in seeking these types of partners. Collaborations are complex and time-consuming arrangements to negotiate and document. To date, our license agreement with Bayer is our only such collaboration. We may not be able to enter into other collaborations on acceptable terms, or at all.

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

- does not have sufficient resources or decides not to devote adequate 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 prospective 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 our clinical studies, the likelihood of approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such product to customers, the potential of competing products, the strength of the intellectual property, other potential sources of market exclusivity for such product, 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. Inadequate capitalization of our company, or the perception thereof, could negatively affect our negotiating leverage in transactions.

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 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, Ovaprene may need to have a typical use efficacy outcome (which is the expected rate of pregnancy protection once the product is used widely under everyday circumstances) comparable to current non-implanted hormonal contraceptive methods (pills, patches and vaginal rings), which is approximately 91% typical use efficacy. 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, the license grant under our agreement with Bayer may never become effective, or, if Bayer elects to make the license grant effective, Ovaprene's commercial success may be limited, and our business prospects could 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, we may not receive regulatory approval to market Sildenafil Cream, 3.6%, or, if approved, many physicians may not prescribe and/or 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 26, 2020, we had 19 employees, of which 15 were full-time and four were 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 product development and operational expertise, and to limit full-time personnel resources. With a small number of employees, our ability to supervise the external consultants and vendors we engage may be constrained, which may impact the timing and quality of services we receive. 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.

In March 2020, we implemented work-from-home and restricted travel policies and, subsequently, the governors of California and Massachusetts, states in which we have operations, issued statewide stay-at-home orders to help combat the spread of COVID-19. In addition, many, if not all, of our consultants, partners and vendors on which we rely heavily have implemented similar policies, are subject to similar orders, and/or may re-allocate resources otherwise intended for our activities to activities intended to address the COVID-19 pandemic. The duration of these policies and of the California and Massachusetts stay-at-home orders currently is indefinite. In addition, we and our consultants, partners and vendors may experience high rates of employee leave during the COVID-19 pandemic due to increased rates of worker or family member illness, school and child care center closures and recent amendments to the Family and Medical Leave Act that, subject to limited exceptions for small employers, allow workers to take up to 12 weeks of job-protected leave through December 2020 if unable to work or telework due to a need to care for children under 18 years of age because that child's school or place of care has closed or child care provider is unavailable due to the COVID-19 pandemic. While we have systems and technologies in place that enable our employees to work from home, state and local stay-at-home orders, work-from-home policies and travel restrictions and employee leaves may adversely affect our ability to effectively manage and operate our business, increase our expenses and may result in delays in our anticipated development program timelines.

If we fail to attract and retain management and other key personnel, we may not successfully complete development of, obtain regulatory approval for or commercialize our 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. In addition, our limited personnel and financial resources may result in greater workloads for our employees compared to those at companies with which we compete for personnel, which may lead to higher levels of employee burnout and turnover. 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 women’s health products 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.

New legal precedent, laws and regulations could make it costlier or more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract or retain qualified persons to serve as our senior management or on our board of directors.

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, 2019, we acquired Microchips, and during the year ended December 31, 2018, we entered into license agreements with each of SST and Catalent 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 if and when we become an "accelerated filer," as defined in rules adopted by the SEC under the Securities Exchange Act of 1934. Under recently adopted SEC rules, generally, we will become an accelerated filer if our public float as of the last business day of June is $75 million or more and we reported annual revenues of $100 million or more for our most recently completed fiscal year. Regardless of whether we become an accelerated filer, we may 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. Even while we have non-accelerated filer status, our management and other personnel will need to continue to devote substantial time towards maintaining compliance with the requirements of being a public company. The Sarbanes-Oxley Act of 2002 and rules and regulations subsequently implemented by the SEC and Nasdaq 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, devote substantial time to these compliance initiatives. Moreover, if and when we become an accelerated filer, our compliance costs will increase.

For example, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we must furnish a report annually by our management on the effectiveness of our internal control over financial reporting, and performing the system and process documentation and evaluation necessary to issue that report requires us to incur substantial expense and expend significant management time. If and when we are an accelerated filer, we will also have to obtain

an attestation report on our internal control over financial reporting by our independent registered public accounting firm, which may substantially increase compliance costs.

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 mitigate 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, including liability under laws that protect the privacy of personal information, 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

We depend heavily on the success of our clinical-stage product candidates, DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%. Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully develop and obtain regulatory approval to market and sell any of these product candidates would likely adversely affect our business.

Our business depends on the successful clinical development and regulatory approval of our 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. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial. Accordingly, while there have been positive results from prior clinical studies of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%, this does not guarantee successful outcomes in future studies of these product candidates. Further, the fact that the active pharmaceutical ingredients in certain of our product candidates, including DARE-BV1 and Sildenafil Cream, 3.6%, have received regulatory approval in other formulations and/or for other indications does not guarantee successful development of our product candidates. Clinical trials may never demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates.

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 to market and sell 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 could have a materially adverse effect on our business prospects, operations and viability.

Our rights to our four clinical-stage product candidates arise from license agreements with third parties, and the loss or impairment of our licensed rights to develop and commercialize these product candidate, including as a result of our inability or other failure to meet our obligations under any one of such license agreements, could have a substantial negative effect on our company's prospects.

We entered into a license agreement with ADVA-Tec for the exclusive worldwide rights to develop and commercialize Ovaprene that became effective in July 2017. 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, (5) fail to conduct certain clinical trials, or (6) fail to make certain milestone, sublicense and/or royalty payments to ADVA-Tec including a milestone payment due upon the FDA's approval to commence a pivotal human clinical trial of Ovaprene, which we expect to occur in the second half of 2020. 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, or any updated development plan approved by the joint development committee, 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 Catalent license agreement under which we acquired exclusive global rights to Catalent's IVR technology platform, including the product candidates we now call DARE-HRT1, DARE-FRT1 and DARE-OAB1. Under this 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 agreement, and Catalent 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-Catalent JNP 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, Catalent, 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 could 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 future product candidates we may seek to develop may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable.

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 could significantly impact our product development costs and timelines, as well as a product candidate's market potential, if ultimately approved. The timing of initiation, conduct and completion of clinical trials and other testing of our product candidates may vary dramatically due to factors within and outside of our control and is difficult to predict accurately. We may make statements regarding anticipated timing for commencement, completion of enrollment, and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons.

In 2020, we intend to commence and complete a pivotal Phase 3 clinical study of DARE-BV1 and a Phase 1 clinical study of DARE-HRT1, and to commence a pivotal clinical study of Ovaprene and a Phase 2b clinical study of Sildenafil Cream, 3.6%. We currently do not have adequate capital to conduct all of these clinical studies in 2020. In addition to lack of adequate capital, commencement and/or completion of these studies may be delayed, terminated or suspended as a result of the occurrence of any of a number of other factors, including the need to obtain authorizations from the FDA and the institutional review boards, or IRBs, of prospective clinical study sites, delayed or inadequate supply of our product candidates or other clinical trial material, slower than expected rates of patient recruitment or enrollment, other factors described below, and unforeseen events. In addition, among other factors, our ability to commence our planned pivotal clinical study of Ovaprene is subject to the FDA's review and clearance of an IDE application.

The commencement of clinical trials of our product candidates can be delayed for many reasons, including delays in:

- obtaining required funding;
- obtaining guidance or authorizations from the FDA or foreign regulatory authorities;
- finalizing the trial design as a result of discussions with the FDA, other regulatory authorities or prospective clinical trial investigators or sites;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining sufficient quantities of our product candidates and other clinical trial material; or
- obtaining IRB approval to conduct a clinical trial at a prospective site.

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:

- lack of adequate funding;
- failure to conduct the clinical trial in accordance with regulatory or IRB 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;
- delayed or insufficient supply of clinical trial material or inadequate quality of such materials;
- failure of our CROs or other third-party contractors to meet their contractual obligations to us in a timely manner, or at all; or
- delays quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

An emerging and uncertain risk to our timelines for commencement and completion of our clinical trials is the COVID-19 pandemic. Our prospective or contracted clinical trial sites may temporarily suspend activities

at their sites to help secure the safety of their employees or to adhere to government recommendations or orders related to social distancing and limiting public gatherings, or they may experience resource constraints stemming from the pandemic and become unable to allocate adequate resources to reach agreements necessary to commence our clinical trials at their facilities or, even if agreements are in place, to conduct our clinical trials. For clinical trials that we are able to initiate, we may experience lower than anticipated subject enrollment and completion rates, including because individuals may avoid medical settings due to concerns related to the pandemic or they may become subject to governmental orders or recommendations that impose curfews or that ask individuals to leave their homes only if essential. In addition, increased rates of worker illness and implementation of work-from-home and restricted travel policies due to the COVID-19 pandemic may delay any regulatory authority and/or IRB approvals necessary for our clinical trials and/or prevent our CROs and other third-party contractors who are necessary for the conduct of our clinical trials from meeting their contractual obligations to us in a timely manner, any of which could delay commencement and completion of our clinical trials.

Significant clinical trial delays also could jeopardize our ability to meet obligations under agreements under which we license our rights to our product candidates, allow other companies to bring competitive products to market before we do, shorten any period of market exclusivity we may otherwise have under our patent rights, and weaken our negotiating position in discussions with potential collaborators, any of which could impair our ability to successfully commercialize our product candidates, if ultimately approved. Any significant delays in commencement or completion of clinical trials of our product candidates, or the suspension or termination of a clinical trial, could materially harm our business, financial condition and results of operations.

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 formulation is designed to provide extended release of the drug at the site of infection over multiple days and require no intervention by the patient beyond the initial application, which we believe 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.

We plan to commence a Phase 3 clinical study of DARE-BV1 for BV in 2020. Based on discussions with the FDA, we believe that if this study is successful, the FDA will not require additional clinical studies to support the NDA for DARE-BV1. However, the FDA may determine that the results of the Phase 3 study are not sufficiently robust or convincing and require additional clinical and/or nonclinical studies prior to approval of DARE-BV1 to treat BV. Additionally, in parallel with the Phase 3 clinical study and to support the NDA, we will conduct nonclinical studies of certain excipients in DARE-BV1 and the clinical formulation of DARE-BV1, including reproductive toxicology studies. If these studies are not completed on schedule or if they provide results that we or the FDA determine to be concerning, this may cause a delay or failure in filing the NDA or obtaining approval for DARE-BV1. If DARE-BV1 receives FDA 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. See also "-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" below.

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 prior determination that Ovaprene has a device-primary mode of action and re-assignment of primary oversight responsibility to CDER would adversely impact our timeline and significantly raise our costs to complete clinical development and obtain regulatory approval for Ovaprene.

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 significantly increase the anticipated cost and

timeline to completion of Ovaprene's development and require us to raise additional funds. For example, we plan to commence a contraceptive effectiveness and safety study of Ovaprene in 2020. Based on discussions with the FDA, we believe that if this study is successful, the FDA will not require additional clinical studies to support the PMA for Ovaprene. However, the FDA may determine that the results of the study are not sufficiently robust or convincing and require additional clinical and/or nonclinical studies prior to approval of Ovaprene. 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 could have a material adverse effect on the prospects for developing Ovaprene, our business and our financial condition. See also "-The commercial success of Ovaprene will depend on market acceptance of a monthly, hormone-free vaginal ring product, availability of alternative contraceptive products and women's preferences, as well as the success of Bayer's marketing and sales efforts" below.

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. While we have worked with experts to develop novel patient reported outcome, or PRO, instruments for our planned Phase 2b study of Sildenafil Cream, 3.6%, tested the proposed PRO instruments in a content validity study, reviewed the results of that study with the FDA and aligned with the FDA on the Phase 2b study design, the Phase 2b study may nevertheless fail to demonstrate effectiveness of Sildenafil Cream, 3.6% in treating FSAD. 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 *in vitro* 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 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. We rely on third parties to supply and manufacture our product candidates and other materials necessary to commence and complete pre-clinical testing, clinical trials and other activities required for regulatory approval of our product candidates. If we receive the requisite regulatory approvals for one or more products, we expect to rely on third parties for commercial 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.

We are responsible for obtaining supplies of DARE-BV1 for the Phase 3 trial to be conducted in the United States. While we believe we will be able to obtain sufficient supplies of raw materials required to produce the clinical trial material, future supplies may be more difficult and costly to obtain. For example, our current supplier of the active ingredient, clindamycin, is located in China. Should this supplier slow its production or shut down its factory in light of the COVID-19 pandemic, or for any reason, we may not be able to obtain an adequate supply. If this were to occur, we would be forced to source clindamycin from a different supplier, which could lead to higher costs and delays in development and regulatory approval of DARE-BV1.

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, delay or suspension of ongoing research, including clinical trials, 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, including due to geopolitical actions, natural disasters or public health emergencies or pandemics, such as the COVID-19 pandemic, we could experience delays in research, planned or ongoing 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, including due to the effects related to geopolitical actions, natural disasters, public health emergencies or pandemics, such as the COVID-19 pandemic, or force majeure events that affect their facilities or ability to perform. 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, until the event that resulted in the delay or interruption is adequately addressed, or until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available, and we may not have recourse against the party who did not perform or terminated their agreement with us if such non-performance or termination is excused under our agreements with such party. 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 rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our development programs. Failure of these third parties to successfully carry out their contractual duties, comply with regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our product development timelines and/or failure of our 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 in clinical development. 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 standards, including due to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic. 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.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, and others, including regulatory authorities, may not agree with our interpretation of study data.

From time to time, we may publicly disclose interim, preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. There can be no guarantee that a favorable futility analysis will result in a favorable final result at the completion of the clinical trial.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of study data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our business depends on obtaining the approval of regulatory authorities, and in particular, 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 product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, release, safety, efficacy, regulatory filings, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, other regulatory authorities in the U.S., and comparable authorities in other countries or jurisdictions where we seek to test or market our product candidates. The process of obtaining marketing approvals, in the U.S. and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. In addition, requirements for approval may change over

time and our current development plans may not accurately anticipate all applicable requirements for marketing approval by the FDA or comparable regulatory authorities for jurisdictions outside the U.S.

Our success depends on our ability to obtain regulatory approvals for our product candidates in a timely and cost-efficient manner. We have not submitted a marketing application or received approval to market any of our product candidates from any regulatory authority. Even if we successfully complete clinical studies, we may experience delays in our efforts to obtain marketing approvals for any of our product candidates. Due to our relatively small number of employees, we expect to rely on CROs and other vendors and consultants to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals. We do not control these third parties and they may not devote sufficient time and resources to our projects, or their performance may be substandard, resulting in submission delays or failure of a regulatory authority to accept our application for filing. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction.

We may change the development plan for a product candidate as a result of changes during the development period in the FDA's marketing approval policies or the amendment or enactment of additional statutes or regulations, or following our review of outcomes of other similar product candidates under development. This could significantly lengthen our development timelines and cost. Further, the FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, changes in the manufacturing process or facilities or clinical trials, even if we had previously aligned with the FDA on such data and other requirements. 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 testing or manufacturing 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.

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 consumers, physicians, other 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;
- availability of alternative products; and
- the convenience and comfort level to consumers provided by our product compared to 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 competitive 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;
- the success or failure of other branded therapies;
- 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.

Additionally, our current commercialization strategy for DARE-BV1 is to partner with one or more pharmaceutical companies with an established commercial infrastructure and expertise. If we are not successful in attracting an acceptable commercialization partner or entering into an agreement with acceptable terms on a timely basis or at all, commercial launch of DARE-BV1 could be significantly delayed. Further, any future collaboration may not be successful, in which case our ability to realize the full market potential of our product could be harmed.

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 market acceptance of a monthly, hormone-free vaginal ring product, availability of alternative contraceptive products and women's preferences, as well as the success of Bayer's marketing and sales efforts.

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.

Under our license agreement with Bayer, provided the license grant becomes effective, Bayer will have exclusive rights to market and sell Ovaprene in the U.S. Accordingly, the potential value of Ovaprene to our company is highly dependent on the efforts and activities of Bayer, and Bayer has significant discretion in determining the resources that it will allocate to commercialization of Ovaprene.

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;
- the success or failure of 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 could be hurt as a result.

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 these product candidates on fetal development has not been studied and there are no adequate or well-controlled studies of these product candidates 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., AbbVie, 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 or a commercial partner 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 or receiving royalties and other payments based on sales by a commercial partners.

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 or a commercial partner 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 or a commercial partner cannot introduce a product, if approved, at our desired price or 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 or royalties and other license fees, as applicable, 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 have been, and may be further, 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 our Microchips contraceptive program, 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 medically critical or essential. 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 by us or a commercial partner 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, or those of a commercial partner, 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, including a commercial partner, regardless of the outcome, would be costly and time consuming, and may negatively affect our results of operations and financial condition.

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. Failure to timely enter into such agreements could delay commercial launch of a product candidate that has received marketing approval. This reliance on third parties will also 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.

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 marketing approval from the FDA for our product candidates, we may fail to receive similar approval outside the United States, which could substantially limit the value of such products.

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. Approval by the FDA or a comparable foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. 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.

Many of our product candidates are in pre-clinical stages of development and may never advance to clinical 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, our pre-clinical stage programs may never progress to clinical development and may prove to be worthless.

Our business may be adversely affected by unfavorable or unanticipated 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) or a global health emergency, 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 or commercialize our 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 our current and any future product candidates, and, if approved, market and sell our products or 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 the Hatch-Waxman Act, 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 the Hatch-Waxman Act 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 the Hatch-Waxman Act 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 the Hatch-Waxman Act, 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 Catalent'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 Act 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. Additionally, our license agreement with Bayer requires that we indemnify Bayer from and against all liabilities, damages, losses and expenses arising from or occurring as a result of development, manufacture, use or commercialization of Ovaprene by us or any licensee of ours, including without limitation, product liability claims, except in limited circumstances. As a result of our indemnification obligations to Bayer and limitations on ADVA-Tec's obligations to indemnify us, any patent infringement litigation relating to Ovaprene could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition.

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 our product candidates 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 product candidates and may harm our business.

Our license agreements with Hammock/MilanaPharm, ADVA-Tec, SST and Catalent 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 agreements with Pear Tree and Microchips, 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 and merger 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 Catalent'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 Catalent, 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 changes to our product development and approval timelines, results from any clinical trial, and communications or decisions from regulator authorities relating to a review of or decisions on applications we submit for our product candidates, in each case particularly those related to our clinical-stage product candidates;
- the amount of our unrestricted cash;
- the level of expenses related to development of our current and future product candidates, and in particular our clinical-stage 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 and effects from geopolitical actions, including war and terrorism, or natural disasters such as earthquakes, typhoons, floods and fires or public health emergencies or pandemics, such as the COVID-19 pandemic;
- 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;
- recommendations or reports issued by securities research 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, including the requirements commonly referred to as the minimum bid price rule and with either the stockholders' equity rule or the market value of listed securities rule. The minimum bid price rule requires that the closing bid price of our common stock be at least $1.00 per share, and the stockholders' equity rule requires that our stockholders' equity be at least $2.5 million, or, alternatively, that the market value of our listed securities be at least $35 million or that we have 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. There can be no assurance we will continue to satisfy applicable continued listing requirements. For example, in both 2018 and 2019, we received letters 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. Additionally, in November 2019, we received a letter from the Nasdaq Staff notifying us that we were not in compliance with the stockholders' equity rule because we reported less than $2.5 million in stockholders' equity as of September 30, 2019 and did not satisfy the alternative standards under Nasdaq Listing Rule 5550(b). We were notified by the Nasdaq Staff in January 2020 that we regained compliance with the minimum bid price rule and, in February 2020, that we regained compliance with the stockholders' equity rule, but there can be no assurance that we will continue to satisfy these or other continued listing standards and maintain the listing of our common stock with Nasdaq.

The suspension or delisting of our common stock, or the commencement of delisting proceedings, 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 suspension or delisting of our common stock, or the commencement of delisting proceedings, 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 potential strategic partners, such as 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. Additionally, past receipt of grant funding may not be predictive of our ability to secure additional grants to fund further development of a program. If our IVR product candidates, DARE-VVA1, the Microchips program, DARE-RH1 or the injectable etonogestrel product candidates we may license from Orbis fail to be valued, our stock price may be adversely affected.

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, since January 1, 2020 and through March 26, 2020, we sold an aggregate of 3.3 million shares of our common stock in at-the-market offerings, we issued approximately 3.0 million shares of our common stock to the former stockholders of Microchips in connection with our acquisition of that company in November 2019, we sold approximately 5.3 million shares of our common stock in an underwritten public offering that closed in April 2019, 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, 2019, there were 1.9 million shares of our common stock subject to outstanding options, almost all of which 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 March 26, 2020, there were approximately 2.0 million shares of our common stock subject to outstanding warrants to purchase common stock, virtually all of which currently have an exercise price of $0.98 per share. 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 shares of our common stock. We refer to this agreement as our "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, 2019, we had outstanding options to purchase up to 1.9 million shares of our common stock and, and as of March 26, 2020, we had outstanding warrants to purchase up to approximately 2.0 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 issued in February 2018 contain price protection in the form of anti-dilution provisions that could harm trading in our shares and make it difficult for us to obtain additional financing.

The warrants 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 26, 2020, February 2018 Warrants to purchase up to approximately 2.0 million shares of our common stock were outstanding and the exercise price of those warrants was $0.98 per share. 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 outstanding 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 a smaller reporting company and a non-accelerated filer and the reduced disclosure requirements available to such companies may make our common stock less attractive to investors.

The SEC established the smaller reporting company, or SRC, category of companies in 2008, and expanded it in 2018, in an effort to provide general regulatory relief for smaller companies. SRCs may choose to comply with scaled financial and non-financial disclosure requirements in their annual and quarterly reports and registration statements relative to non-SRCs. In addition, companies that are not "accelerated filers" can take advantage of additional regulatory relief. Whether a company is an accelerated filer or a SRC is determined on an annual basis. For so long as we qualify as a non-accelerated filer and/or a SRC, we will be permitted to and we intend to rely on some or all of the accommodations available to such companies. These accommodations include:

- not being required to provide an auditor's attestation of management's assessment of internal control over financial reporting required by Section 404(b) of the Sarbanes-Oxley Act of 2002;
- reduced financial disclosure obligations, including that SRCs need only provide two years of financial statements rather than three years; a maximum of two years of acquiree financial statements are required rather than three years; fewer circumstances under which pro forma financial statements are required; and less stringent age of financial statements requirements;
- reduced non-financial disclosure obligations, including regarding the description of their business, management's discussion and analysis of financial condition and results of operations, market risk, executive compensation, transactions with related persons, and corporate governance; and
- later deadlines for the filing of annual and quarterly reports compared to accelerated filers.

We will continue to qualify as a SRC and non-accelerated filer for so long as (a) our public float is less than $75 million as of the last day of our most recently completed second fiscal quarter or (b) our public float is $75 million or more but less than $700 million and we reported annual revenues of less than $100 million for our most recently completed fiscal year.

We may choose to take advantage of some, but not all, of the available accommodations. We cannot predict whether investors will find our common stock less attractive if we rely on these accommodations. 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.

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 our 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 we fail to attract securities analysts to publish research on our business or if they publish or convey negative evaluations of our business, 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 real property to support our business. The office space for our corporate headquarters, which is in good operating condition, is in San Diego, California. We believe that the real property we lease meets our current needs and that we will be able to renew our lease when needed on acceptable terms or find alternative facilities.

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 us.

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

Our common stock is listed on the Nasdaq Capital Market under the symbol “DARE.”

Holders of Common Stock

As of March 26, 2020, we had approximately 59 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 acceleration of innovative products for women’s health. We are driven by a mission to identify, acquire and develop a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, fertility, and sexual and vaginal health. Our business strategy is to in-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, and then out-license these products to companies with sales and distribution capabilities in women's health to leverage their commercial capabilities. We and our wholly owned subsidiaries operate in one business segment.

Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through mid- and late stages of clinical development or approval. Our global commercialization and development strategy involves partnering with pharmaceutical companies and regional distributors with established marketing and sales capabilities in women's health, including through co-development and promotion agreements, once we have advanced a candidate through mid- to late-stage clinical development.

Our portfolio includes three product candidates in advanced clinical development:

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis, or BV;
- **Ovaprene®**, a hormone-free, monthly vaginal contraceptive; and
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina for treatment of female sexual arousal disorder, or FSAD.

Our portfolio also includes three product candidates that we believe are Phase 1-ready:

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring for the treatment of vasomotor symptoms (VMS) as part of a hormone replacement therapy, or HRT, following menopause;
- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone- receptor positive breast cancer; and
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an in vitro fertilization treatment plan.

See “ITEM 1. BUSINESS-Our Clinical-Stage Product Candidates and Programs,” in Part I of this report for additional information regarding our product candidates.

Our primary operations have consisted of, and are expected to continue to consist of, product research and development and advancing our portfolio of product candidates through clinical development and regulatory approval. We expect that the majority of our development expenses over the next two years will support the advancement of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%.

To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any revenue. We are 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. We are 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.

In addition, the COVID-19 pandemic continues to rapidly evolve. We do not yet know the full extent of its potential effects on our business, including the anticipated aggregate costs for development of our product candidates, on our anticipated timelines for the development of our product candidates, or on the supply chain for our clinical supplies. However, these effects could have a material adverse impact on our business and financial condition.

Recent Events

Microchips Acquisition

On November 20, 2019, we acquired Microchips Biotech, Inc. via a merger. We issued an aggregate of approximately 3.0 million shares of our common stock to the holders of shares of Microchips’ capital stock outstanding immediately prior to the effective time of the merger and we agreed to pay them: (1) contingent consideration of up to $46.5 million upon the achievement of specified funding, product development and regulatory milestones; (2) contingent consideration of up to $55.0 million upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property we acquired in the merger; (3) tiered royalty payments based on annual net sales of such products; and (4) a percentage of sublicense revenue related to such products. We expect that approximately $1.0 million of the contingent consideration may become payable through 2021. For additional information regarding this transaction, see “ITEM 1. BUSINESS-Microchips Acquisition” in Part I of this report.

License Agreement with Bayer HealthCare

On January 10, 2020 we entered into a license agreement with Bayer HealthCare LLC regarding the further development and commercialization of Ovaprene in the U.S. We received a $1.0 million upfront payment from Bayer and Bayer will support us in development and regulatory activities by providing the equivalent of two experts to advise us in clinical, regulatory, preclinical, commercial, CMC and product supply matters. Bayer, in its sole discretion, has the right to make the license effective by paying us an additional $20.0 million, referred to as the "Clinical Trial and Manufacturing Activities Fee" Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with us with regard to development. We will also be entitled to receive (a) milestone payments totaling up to $310.0 million if all such milestones are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue. For additional information regarding the Bayer license agreement, see "ITEM 1. BUSINESS-License Agreements-Bayer HealthCare License Agreement" in Part I of this report.

Financial Overview

Revenue

To date we have not generated any revenue. In the future, and if we are successful in advancing our product candidates through late stages of clinical development, we may generate revenue from license fees, milestone payments, research and development payments in connection with strategic partnerships, as well as royalties and commercial milestones resulting from the sale of products. Our ability to generate such revenue will depend on the successful clinical development of our product candidates, the receipt of regulatory approvals to market such products and the eventual successful commercialization of product candidates. If we fail to complete the development of product candidates in a timely manner, or to 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 nonclinical studies and clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies;
- transaction costs related to acquisitions of companies, technologies and related intellectual property, and other assets;
- internal costs that are associated with activities performed by our research and development organization and generally benefit multiple programs.

In 2019, our research and development expenses consisted primarily of costs associated with continued development of DARE-BV1, Ovaprene, Sildenafil Cream 3.6% and DARE-HRT1. We expect research and development expenses to increase in the future as we continue to 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 to licensors. 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.

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.

Critical Accounting Policies and Estimates

Management's discussion and analysis of financial condition and results of operations is based on our financial statements that we prepared in accordance with accounting principles generally accepted in the United States. Preparing these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. Historically, revisions to our estimates have not resulted in a material change to the financial statements. The items in our financial statements requiring significant estimates and judgments are as follows: the fair value of stock-based compensation, goodwill impairment and purchase accounting.

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.

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.

Acquired In-Process Research and Development Expense

We have acquired, and may continue to acquire, the rights to develop new product candidates. Payments to acquire a new product candidate, as well as future milestone payments associated with asset acquisitions which are deemed probable of achievement, are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Results of Operations

Comparison of the Years ended December 31, 2019 and 2018

The following table summarizes our consolidated results of operations for the years ended December 31, 2019 and 2018, together with the changes in those items in dollars:

	Years Ended December 31,		Dollar
	2019	2018	Change
Operating expenses:			
General and administrative	$ 5,265,438	$ 4,655,837	$ 609,601
Research and development	8,546,108	6,413,956	2,132,152
License expenses	533,334	625,000	(91,666)
Impairment of goodwill	—	5,187,519	(5,187,519)
Loss from operations	(14,344,880)	(16,882,312)	(2,537,432)
Other income	81,050	143,497	(62,447)
Net loss	$ (14,263,830)	$ (16,738,815)	$ (2,474,985)

Revenues

We did not recognize any revenue for the years ended December 31, 2019 or 2018.

General and administrative

The increase of $609,601 in general and administrative expenses from 2018 to 2019 was primarily attributable to: (i) an increase in personnel costs of approximately $482,000 reflecting the hiring of additional employees which resulted in increased salary, benefit and bonus expenses , (ii) an increase in stock-based compensation expense of approximately $241,000, (iii) an increase in insurance costs of approximately $102,000, (iv) an increase in rent expense of approximately $79,000 due to the addition of two leases acquired in conjunction with the acquisition of Microchips, (v) an increase of approximately $38,000 of advertising and marketing expenses, and (vi) an increase of approximately $48,000 in expense related to conferences and seminars. Those increases were partially offset by a decrease of approximately $410,000 in expenses for accounting, legal, and professional services.

Research and development

The increase of approximately $2.1 million in research and development expenses from 2018 to 2019 was primarily attributable to (i) an increase in costs related to development activities of approximately $2.3 million for DARE-BV1, Ovaprene, DARE-HRT1, DARE-FRT1 and Sildenafil Cream, 3.6%, (ii) an increase in personnel costs of approximately $875,000 reflecting the hiring of additional employees which resulted in increased salary, benefit and bonus expenses, and (iii) an increase in stock-based compensation expense of approximately $82,000. Those increases were partially offset by (x) an increase in grant funding recorded as a reduction to research and development expense related to Ovaprene of approximately $894,000, (y) a decrease in costs related to development activities of approximately $285,000 for DARE-VVA1, and (z) a decrease in costs related to pre-clinical development activities of approximately $40,000. We expect research and development expense to increase significantly in 2020 as we continue to develop our product candidates and as we achieve development milestones for which we have related payment obligations.

License expenses

The $91,666 decrease in license expenses from 2018 to 2019 was attributable to a decrease in license fees paid. During 2018, we paid $625,000 in connection with entering into license agreements for DARE-HRT1, Sildenafil Cream, 3.6% and DARE-BV1. During 2019, we accrued or paid $533,334 of license fees due under our license agreements related to DARE-BV1 and DARE-HRT1.

Goodwill impairment expense

The goodwill impairment expense for the year ended December 31, 2018 was 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

The decrease of $62,447 in interest income from 2018 to 2019 was primarily due to a decrease in interest earned on cash balances in the current year.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

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. 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. 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.

At December 31, 2019, our accumulated deficit was approximately $44.0 million, our cash and cash equivalents were approximately $4.8 million, and our working capital was approximately $0.8 million. For the year ended December 31, 2019, we incurred a net loss of $14.3 million and had negative cash flow from operations of approximately $13.3 million.

The cash used to fund our operations comes from a variety of sources. In April 2019, we received gross proceeds of approximately $5.8 million, and net proceeds of approximately $5.2 million after deducting underwriting

discounts and offering expenses, in an underwritten public offering. In November 2019, we received approximately $6.1 million in cash and cash equivalents in connection with our acquisition of Microchips. During 2019, we received approximately $1.0 million under an existing grant from the National Institutes of Health that funded a portion of the postcoital clinical study costs of Ovaprene. From January 1, 2020 and through March 26, 2020, we received approximately $8.1 million in gross cash proceeds: (1) a $1.0 million upfront payment under our license agreement with Bayer HealthCare, LLC, (2) approximately $5.4 million from the sales of an aggregate of 3,308,003 shares of our common stock in at-the-market offerings; and (3) approximately $1.7 million upon the exercise of warrants to purchase 1.7 million shares of our common stock.

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 significantly in 2020 as we continue the development of our product candidates, in particular as we conduct activities in preparation for and commence and conduct our planned pivotal clinical study of DARE-BV1, Phase 2b clinical study of Sildenafil Cream, 3.6%, pivotal contraceptive effectiveness and safety study of Ovaprene, and a Phase 1 clinical study of DARE-HRT1, as discussed above, and as we incur license expenses associated therewith.

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, particularly in light of the effects that the COVID-19 pandemic has recently had on the capital markets and investor sentiment. 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,	
	2019	2018
Net cash used in operating activities	$ (13,315,480)	$ (10,268,425)
Net cash provided by (used in) investing activities	6,143,893	(518,836)
Net cash provided by financing activities	5,151,702	10,111,952
Effect of exchange rate changes on cash and cash equivalents	(5,897)	(78,648)
Net increase (decrease) in cash	$ (2,025,782)	$ (753,957)

Operating activities

Cash used in operating activities during the year ended December 31, 2019 included a net loss of $14.3 million, decreased by non-cash stock-based compensation expense of $462,239. Components providing operating cash were a $621,618 increase in accrued expenses, an increase of $608,650 in accounts payable, and an increase of $237,937 in other non-current assets and deferred charges. Components reducing operating cash were a $322,482 increase in prepaid expenses, a $238,109 increase in deferred grant funding, and a $201,423 increase in other receivables.

Cash used in operating activities during the year ended December 31, 2018 included a net loss of $16.7 million, decreased by non-cash impairment of goodwill of $5.2 million acquired in-process research and development expense of approximately $507,000 and non-cash stock-based compensation expense of $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.

Investing activities

Cash provided by investing activities during the year ended December 31, 2019 consisted of the existing cash balances of Microchips as of the acquisition date of approximately $6.1 million.

Cash used in investing activities during the year ended December 31, 2018 consisted primarily of approximately $500,000 of transaction costs associated with our acquisition of Pear Tree.

Financing activities

Cash provided by financing activities during the year ended December 31, 2019 consisted of proceeds from the underwritten public offering completed in April 2019.

Cash provided by financing activities during the year ended December 31, 2018 consisted of $10.1 million of net proceeds from the underwritten offering completed in February 2018 and sales under the common stock sales agreement completed in January and February of 2018.

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, 2019, 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, 2019 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 internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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, 2019 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.

Under SEC rules, because we are a non-accelerated filer, we are not required to provide an auditor attestation report on internal control over financial reporting, nor did we engage our independent registered public accounting firm to perform an audit of 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 fourth quarter ended December 31, 2019 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 “Board of Directors,” “Corporate Governance,” 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, 2019 and is incorporated in this report by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the sections titled “Board of Directors" and "Executive 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 "Board of Directors" and “Certain Relationships and Related Transactions” 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 Independent Auditor” 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	
2.3+	Agreement and Plan of Merger, dated November 10, 2019, Dare Bioscience, Inc., MC Merger Sub, Inc., Microchips Biotech, Inc., and Shareholder Representative Services LLC, as the stockholders' representative	8-K	001-36395	11/12/2019	2.1	
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	
4.6	Description of securities of the registrant					X
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 Daré 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 Daré 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 Catalent JNP, Inc. (fka 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	10-K	001-36395	04/01/2019	10.10(a)	
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	10-K	001-36395	04/01/2019	10.10(b)	
10.10(c)	Amendment No. 1 to Assignment Agreement entered into as of December 4, 2019 between Daré Bioscience, Inc. and Hammock Pharmaceuticals, Inc.					X
10.10(d)	Amendment No. 2 to the License Agreement entered into as of December 3, 2019 between 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	
10.15*	Daré Bioscience, Inc. Performance Bonus Plan	10-Q	001-36395	11/12/2019	10.1	
10.16+	License Agreement dated as of January 10, 2020 between Bayer HealthCare LLC and Daré Bioscience, Inc.					X
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.

+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

* 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: March 27, 2020

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	March 27, 2020
/s/ LISA WALTERS-HOFFERT Lisa Walters-Hoffert	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 27, 2020
/s/ WILLIAM H. RASTETTER William H. Rastetter, Ph.D.	Chairman of the Board and Director	March 27, 2020
/s/ CHERYL R. BLANCHARD Cheryl R. Blanchard, Ph.D.	Director	March 27, 2020
/s/ JESSICA D. GROSSMAN Jessica D. Grossman, M.D.	Director	March 27, 2020
/s/ SUSAN L. KELLEY Susan L. Kelley, M.D.	Director	March 27, 2020
/s/ GREGORY W. MATZ Gregory W. Matz	Director	March 27, 2020
/s/ ROBIN STEELE Robin Steele, J.D., L.L.M.	Director	March 27, 2020

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2019, 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 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 financial statements. The 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.

March 27, 2020
San Diego, California

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

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31,	
	2019	2018
Assets		
Current Assets		
Cash and cash equivalents	$ 4,780,107	$ 6,805,889
Other receivables	555,210	31,037
Prepaid expenses	1,108,615	403,097
Total current assets	6,443,932	7,240,023
Property and equipment, net	63,531	9,396
Other non-current assets	935,325	577,968
Total assets	$ 7,442,788	$ 7,827,387
Liabilities and stockholders' equity		
Current Liabilities		
Accounts payable	$ 1,083,183	$ 459,705
Accrued expenses	2,098,653	631,351
Deferred grant funding	2,019,674	—
Current portion of lease liabilities	410,896	—
Total current liabilities	5,612,406	1,091,056
Contingent consideration non-current	1,000,000	—
Lease liabilities long-term	389,556	9,711
Total liabilities	7,001,962	1,100,767
Commitments and contingencies (Note 10)		
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, 19,683,401 and 11,422,161 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	1,968	1,143
Accumulated other comprehensive loss	(102,625)	(96,728)
Additional paid-in capital	44,564,674	35,791,972
Accumulated deficit	(44,023,191)	(28,969,767)
Total stockholders' equity	440,826	6,726,620
Total liabilities and stockholders' equity	$ 7,442,788	$ 7,827,387

See Accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,	
	2019	**2018**
Operating expenses		
General and administrative	$ 5,265,438	$ 4,655,837
Research and development expenses	8,546,108	6,413,956
License expenses	533,334	625,000
Impairment of goodwill	—	5,187,519
Total operating expenses	14,344,880	16,882,312
Loss from operations	(14,344,880)	(16,882,312)
Other income	81,050	143,497
Net loss	$ (14,263,830)	$ (16,738,815)
Deemed dividend from trigger of round down provision feature	(789,594)	—
Net loss to common shareholders	(15,053,424)	(16,738,815)
Foreign currency translation adjustments, net of tax	(5,897)	(78,648)
Comprehensive loss	$ (15,059,321)	$ (16,817,463)
Loss per common share - basic and diluted	$ (0.97)	$ (1.57)
Weighted average number of common shares outstanding:		
Basic and diluted	15,578,959	10,732,421

See Accompanying Notes to Consolidated Financial Statements.

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, 2017	**6,047,161**	**$ 605**	**$ 25,541,210**	**$ (18,080)**	**$ (12,230,952)**	**$ 13,292,783**
Issuance of common stock	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**
Issuance of common stock via public offering, net	5,261,250	525	5,151,177	—	—	5,151,702
Equity issued in consideration of acquisition	2,999,990	300	2,369,692	—	—	2,369,992
Stock-based compensation	—	—	462,239	—	—	462,239
Deemed dividend from trigger of down round provision	—	—	789,594	—	(789,594)	—
Net loss	—	—	—	—	(14,263,830)	(14,263,830)
Foreign currency translation adjustments	—	—	—	(5,897)	—	(5,897)
Balance at December 31, 2019	**19,683,401**	**$ 1,968**	**$ 44,564,674**	**$ (102,625)**	**$ (44,023,191)**	**$ 440,826**

See Accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,	
	2019	2018
Operating activities:		
Net loss	$ (14,263,830)	$ (16,738,815)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	11,137	2,440
Stock-based compensation	462,239	139,348
Non-cash operating lease cost	(29,121)	9,319
Acquisition-related IPR&D	(202,096)	507,000
Impairment of goodwill	—	5,187,519
Changes in operating assets and liabilities, net of impact of acquisition:		
Other receivables	(201,423)	253,169
Prepaid expenses	(322,482)	(91,526)
Other current assets	—	193,495
Other non-current assets and deferred charges	237,937	145,223
Accounts payable	608,650	151,486
Accrued expenses	621,618	(27,083)
Deferred grant funding	(238,109)	—
Net cash used in operating activities	(13,315,480)	(10,268,425)
Investing activities:		
Acquisition of Microchips cash	6,143,893	—
Purchases of property and equipment	—	(11,836)
Acquisition of Pear Tree and Hydra assets	—	(507,000)
Net cash provided by (used in) investing activities	6,143,893	(518,836)
Financing activities:		
Net proceeds from issuance of common stock and warrants	5,151,702	10,111,950
Net cash provided by financing activities	5,151,702	10,111,952
Effect of exchange rate changes on cash and cash equivalents	(5,897)	(78,648)
Net change in cash and cash equivalents	(2,025,782)	(753,957)
Cash and cash equivalents, beginning of year	6,805,889	7,559,846
Cash and cash equivalents, end of year	$ 4,780,107	$ 6,805,889
Supplemental disclosure of non-cash operating, investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ 583,697	$ —
Deemed dividend from trigger of down round provision	$ 789,594	$ —
Microchips acquisition consideration paid in equity	$ 2,369,992	$ —

See Accompanying Notes to Consolidated Financial Statements.

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and business

Daré Bioscience, Inc. is a clinical-stage biopharmaceutical company committed to the acceleration of innovative products for women's health. Daré Bioscience, Inc. and its wholly owned subsidiaries operate 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 novel 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 in-license or otherwise acquire the rights to differentiated product candidates in the Company's areas of focus, 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.

Since July 2017, the Company has assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While the Company will continue to assess opportunities to expand its portfolio, its current focus is on advancing its existing product candidates through mid- and late stages of clinical development or approval. The Company's global commercialization and development strategy involves partnering with pharmaceutical companies and regional distributors with established marketing and sales capabilities in women's health, including through co-development and promotion agreements, once the Company has advanced a candidate through mid- to late-stage clinical development.

The Company's portfolio includes three product candidates in advanced clinical development:

- **DARE-BV1**, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis, or BV;
- **Ovaprene®**, a hormone-free, monthly vaginal contraceptive;
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina for treatment of female sexual arousal disorder, or FSAD;

The Company's portfolio also includes three product candidates that it believes are Phase 1-ready:

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring for the treatment of vasomotor symptoms (VMS) as part of a hormone replacement therapy, or HRT, following menopause;
- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy, or VVA, in patients with hormone- receptor positive breast cancer; and
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an in vitro fertilization treatment plan.

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

- A microchip-based, implantable drug delivery system and a contraceptive application of that technology utilizing levonorgestrel that is designed to provide user-controlled, long-acting, reversible contraception
- **ORB-204 and ORB-214**, 6-month and 12-month formulations of injectable etonogestrel for contraception; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

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. We expect that the majority of our development expenses over the next two years will support the advancement of DARE-BV1, Ovaprene, and Sildenafil Cream, 3.6%.

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.

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. 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.

As of December 31, 2019, the Company had an accumulated deficit of approximately $44.0 million, had cash and cash equivalents of approximately $4.8 million, and working capital was approximately $0.8 million. For the year ended December 31, 2019, the Company incurred a net loss of $14.3 million and had negative cash flow from operations of approximately $13.3 million.

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 the Company's current operating plan estimates, the Company does not have sufficient cash to satisfy its working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying financial statements. The Company needs to raise substantial additional capital to continue to fund its operations and to successfully execute its current operating plan, including to continue the planned development of DARE-BV1, Ovaprene, and Sildenafil Cream, 3.6%.

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. These consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. One wholly owned subsidiary, Daré Bioscience Australia Pty LTD, operates primarily in Australia. 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 grants issued by a division of the National Institutes of Health and the Bill & Melinda Gates Foundation, or the Gates Foundation. 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 years ended December 31, 2019 and December 31, 2018, the Company recognized approximately $1.2 million and $225,000, respectively, in the statement of operations as a reduction to research and development expense. Grant funding payments received in advance of research and development expenses incurred are recorded as deferred grant payments liability in the Company's consolidated balance sheets.

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. The Company's wholly owned subsidiary, Microchips Biotech, Inc., has a $35,903 letter of credit related to the lease of real property that serves as security for future default of lease payments. The letter of credit is collateralized by cash which is unavailable for withdrawal or for usage for general obligations and is included in cash and cash equivalents on the Company's consolidated balance sheet.

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 $4.8 million and $6.8 million measured at fair value as of December 31, 2019 and 2018, respectively, are classified within Level 1. Other receivables and prepaid expenses 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. The estimated fair value of the $1.0 million of contingent consideration potentially payable by the Company related to its acquisition of Microchips Biotech, Inc. is recorded using significant unobservable measures and other fair value inputs and is therefore classified as a Level 3 financial instrument.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use, or ROU, lease assets, current portion of lease obligations, and long-term lease obligations on the Company's balance sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term. Lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and lease obligations are recognized at the commencement date of the applicable lease based on the present value of lease payments over the lease term. If the lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease asset includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease and the related payments are only included in the lease liability when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. (See Note 9, Leased Properties.)

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.

Acquired In-Process Research and Development Expense

The Company has acquired, and may continue to acquire, the rights to develop new product candidates. Payments to acquire a new product candidate, as well as future milestone payments associated with asset acquisitions which are deemed probable of achievement, are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

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.

The Company tests its goodwill for impairment at least annually as of December 31st 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.

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 CROs, 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.

There were stock options exercisable into 1,889,775 and 1,635,790 shares of common stock outstanding at December 31, 2019 and 2018, 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, 2019, the Company did not record any liabilities for uncertain tax positions.

During 2019, the Company recorded no provision for income taxes. During 2018, the Company recorded a provision for income taxes of $3,200. Management evaluated the Company’s tax positions and, as of December 31, 2019, the Company has approximately $935,000 of unrecognized benefits. The tax years 2015 to 2019 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, 2019, 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, 2019 and 2018, no amounts have been accrued related to such indemnification provisions.

Recently Adopted Accounting Standards

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 became effective for the Company on January 1, 2019 and was adopted using a modified retrospective approach and the effective date is as of the initial application. Consequently, financial information was not updated, and the disclosures required under ASU 2016-02 are not 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 elected 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 recorded approximately $232,000 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. There are no changes to the statement of operations or cash flows as a result of the adoption.

2. **ACQUISITIONS**

Cerulean/Private Daré Stock Purchase Transaction

In July 2017, the Company completed its business combination with Daré Bioscience Operations, Inc., a privately held Delaware corporation, or Private Daré in which Private Daré stockholders sold their shares 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. 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 was primarily attributable to the cash and cash equivalents at closing of the transaction of approximately $9.9 million and the impact of the unamortized fair value of stock options granted by Cerulean that were outstanding immediately before the transaction closed of approximately $3.7 million.

The 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 Acquisition

In May 2018, the Company acquired Pear Tree Pharmaceuticals, Inc., via a merger transaction in which a wholly owned subsidiary the Company, formed for purposes of this transaction, merged with and into Pear Tree, and Pear Tree survived as 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 accounted for the transaction as an asset acquisition as the purchase primarily related to one asset. Transaction costs of approximately $452,000 associated with the acquisition are included in the Company's research and development expense.

In accordance with the terms of the merger agreement that governed the acquisition, because, at the time of the closing of the merger, the sum of (a) certain Pear Tree indebtedness and transaction expenses, the stockholders' representatives' transaction expenses, and amounts payable under Pear Tree's management incentive plan, exceeded the sum of (b) $75,000 and the cash and cash equivalents held by Pear Tree at the closing, the excess amount (approximately $132,000) offset the $75,000 payment due on the one-year anniversary of the closing of the merger to certain former and continuing Pear Tree service providers and former holders of Pear Tree's capital stock and the balance will offset future payments otherwise due under the merger agreement to such parties.

Microchips Acquisition

In November 2019, the Company acquired Microchips Biotech, Inc., or Microchips, via a merger transaction in which a wholly owned subsidiary the Company, formed for purposes of this transaction, merged with and into Microchips, and Microchips survived as the Company's wholly owned subsidiary. Microchips is developing a proprietary, microchip-based, implantable drug delivery system designed to store and precisely deliver numerous therapeutic doses over months and years on a schedule determined by the user and controlled via wireless remote. Microchips' lead product candidate is a pre-clinical stage contraceptive application of that technology that utilizes levonorgestrel.

The Company issued an aggregate of 2,999,990 shares of its common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger. The transaction was valued at $2.4 million, based on the fair value of the 2,999,990 shares issued of $0.79 per share, which was the closing price per share of the Company's common stock on the date of closing. The shares were issued in exchange for Microchips' cash and cash equivalents of $6.1 million, less net liabilities of $3.5 million and transaction costs of $202,000, which was allocated based on the relative fair value of the assets acquired and liabilities assumed.

The Company also agreed to pay (1) contingent consideration based upon the achievement of specified funding, product development and regulatory milestones, and upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property the Company acquired in the merger, (2) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, and (3) a percentage of sublicense revenue related to such products. The Company recorded $1.0 million in contingent consideration associated with milestone payments expected to become payable through 2021.

The Company determined the transaction was accounted for as an asset acquisition as there were no outputs or substantive processes in existence as of the acquisition date. Transaction costs of approximately $202,000 associated with the merger are included in the Company's research and development expense.

3. PREPAID EXPENSES

Prepaid expenses consisted of the following:

	As of December 31,	
	2019	2018
Prepaid clinical expense	$ 305,135	$ 14,547
Prepaid insurance expense	417,152	321,546
Prepaid legal and professional expenses	386,328	67,004
Total prepaid expenses	$ 1,108,615	$ 403,097

4. OTHER NON-CURRENT ASSETS

Other non-current assets consisted of the following:

	As of December 31,	
	2019	2018
Prepaid insurance, long-term portion	$ 404,141	$ 562,266
Deposits	42,904	15,702
Operating lease assets	488,280	—
Total other non-current assets	$ 935,325	$ 577,968

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2019	2018
Accrued compensation and benefits expenses	$ 715,201	$ 416,234
Accrued legal and professional expenses	412,584	32,457
Accrued license expense	280,833	—
Accrued clinical and related expenses	690,035	182,660
Total accrued expenses	$ 2,098,653	$ 631,351

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,	
	2019	2018
Domestic	$ 13,800	$ 16,707
Foreign	464	107
Loss before taxes	$ 14,264	$ 16,814

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, 2019 and 2018 are as follows:

	Years Ended December 31,	
	2019	2018
Federal statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	7.01 %	2.42 %
Permanent differences	(0.02)%	0.31 %
Research and development credit	1.46 %	1.24 %
Stock compensation	(0.44)%	(0.08)%
Other	(0.1)%	— %
Goodwill impairment	— %	(6.48)%
Change in valuation allowance	(28.94)%	(18.43)%
Effective income tax rate	(0.02)%	(0.02)%

The major components of the Company's deferred tax assets as of December 31, 2019 and 2018 are shown below (in thousands).

	2019	2018
Net operating loss carryforwards	$ 46,120	$ 40,436
Research and development credit carryforwards	3,669	3,321
Capitalized research and development costs	11,123	13,334
Other	271	11
Stock compensation	1,987	1,941
Total deferred tax assets	63,170	59,043
Valuation allowance	(63,170)	(59,043)
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 $63.2 million and $59.0 million was established at December 31, 2019 and 2018 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 $4.1 million for the year ending December 31, 2019 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, 2018 is primarily related to an increase in net operating losses generated during the year.

The Company has U.S. federal net operating loss, or NOL, carryforwards available at December 31, 2019 of approximately $174.5 million (2018– $153.8 million) of which, $135.0 million begin expiring in 2027 unless previously utilized and $39.5 million that do not expire but are limited to 80% of taxable income in a given year. The Company has state NOL carryforwards of $140.1 million (2018 – $119.9 million) that begin expiring in 2032 unless previously utilized. The Company has U.S. federal research credit carryforwards available at December 31, 2019 of approximately $2.5 million (2018 – $2.2 million) that begin expiring in 2027 unless previously utilized. The Company has state research credit carryforwards of $1.2 million (2018 – $1.1 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 (in thousands):

	Years Ended December 31,	
	2019	2018
Beginning uncertain tax benefits	$ 924	$ 846
Current year - increases	83	78
Prior year - reductions	(72)	—
Ending uncertain tax benefits	$ 935	$ 924

Included in the balance of uncertain tax benefits at December 31, 2019 are $935,000 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, 2019 and 2018, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The tax years 2015 through 2019 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, 2019.

7. STOCKHOLDERS’ EQUITY

ATM Sales Agreement

In January 2018, the Company entered into a common stock sales agreement under which the Company may sell shares of its 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 2018, the Company 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. The Company did not sell any shares under this agreement during 2019.

April 2019 Underwritten Public Offering

In April 2019, the Company closed an underwritten public offering of 4,575,000 shares of its common stock at a public offering price of $1.10 per share. The Company granted the underwriters a 30-day over-allotment option to purchase up to an additional 686,250 shares which was exercised in full on April 12, 2019. Including the over-allotment shares, the Company issued a total of 5,261,250 shares in the offering and received gross proceeds of approximately $5.8 million and net proceeds of approximately $5.2 million after deducting underwriting discounts and offering expenses.

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 initially had an exercise price of $3.00 per share and are exercisable through February 2023. 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 reduced each time the Company issues or sells (or is deemed to issue or sell) securities for a consideration per share less than the exercise price of those warrants in effect immediately prior to such issuance or sale. 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.

In April 2019, in accordance with the price-based anti-dilution provision discussed above, as a result of the sale of shares in the April 2019 underwritten offering, the exercise price of these warrants was automatically reduced to $0.98 per share. For the year ended December 31, 2019, the Company recorded $0.8 million to additional paid-in capital as a result of that exercise price reduction.

No warrants were exercised during the year ended December 31, 2019 or 2018. As of December 31, 2019, 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

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, 2019. The issued and outstanding common stock of the Company consisted of 19,683,401 and 11,422,161 shares with a par value of $0.0001 as of December 31, 2019 and 2018, respectively. There were no shares of preferred stock outstanding as of December 31, 2019 or 2018.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2019:

Common stock reserved for issuance upon exercise of warrants outstanding	3,750,833
Common stock reserved for issuance upon exercise of options outstanding	1,889,775
Common stock reserved for future equity awards (under the Amended 2014 Plan)	634,294
Total	6,274,902

8. STOCK-BASED COMPENSATION

The 2015 Employee, Director and Consultant Equity Incentive Plan

Prior to the Cerulean/Private Daré stock purchase transaction, Private Daré maintained the 2015 Employee, Director and Consultant Equity Incentive Plan, or the 2015 Private Daré Plan. Upon closing of the Cerulean/Private Daré stock purchase transaction, the Company assumed the 2015 Private Daré Plan and each then outstanding award granted thereunder, which consisted of options and restricted stock. Based on the exchange ratio for the Cerulean/Private Daré stock purchase transaction and after giving effect to the 1-for-10 reverse stock split effected in connection with the closing of that transaction, the outstanding options and restricted stock awards granted under the 2015 Private Daré Plan were replaced with options to purchase 10,149 shares of the Company's common stock with a correspondingly adjusted exercise price, all of which were outstanding as of December 31, 2019 and 223,295 shares of the Company's common stock. Those options are fully vested and expire in December 2025.

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

The Company's 2014 Employee Stock Purchase Plan, or the ESPP, became effective in April 2014, but no offering period has been initiated thereunder since January 2017 and there was no stock-based compensation related to the ESPP for the years ended December 31, 2019 or December 31, 2018.

Amended and Restated 2014 Stock Incentive Plan

The Company maintains the Amended and Restated 2014 Plan, or the Amended 2014 Plan. There were 2,046,885 shares of common stock authorized for issuance under the Amended 2014 Plan when it was approved by the Company's stockholders in July 2018. The number of authorized shares increases 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. As a result of the foregoing, the number of shares available under the Amended 2014 Plan increased by 456,886 to 878,130 on January 1, 2019, which increase represented 4% of the number of outstanding shares of common stock on such date.

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, 2019 and 2018. The exercise price of all options granted during the years ended December 31, 2019 and 2018 was equal to the market value of the Company's common stock on the date of grant. As of December 31, 2019, unamortized stock-based compensation expense of approximately $1.1 million will be amortized over the weighted average period of 2.6 years. As of December 31, 2019, 634,294 shares of common stock were reserved for future issuance under the Amended 2014 Plan, and options to purchase 1,889,775 shares of the Company's common stock granted under the Amended 2014 Plan were outstanding.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	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		
Granted	832,500	0.79		
Exercised	—	—		
Canceled/forfeited	(578,445)	28.52		
Expired	(70)	59.48		
Outstanding at December 31, 2019 (1)	1,889,775	$ 1.21	8.88	$ 46,599
Options exercisable at December 31, 2019	490,513	$ 1.99	8.63	$ 16,091
Options vested and expected to vest at December 31, 2019	1,889,775	$ 1.21	8.88	$ 46,559

(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 statements of operations is as follows:

	Years Ended December 31,	
	2019	2018
Research and development	$ 107,142	$ 24,929
General and administrative	355,097	114,419
Total	$ 462,239	$ 139,348

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, 2019 and 2018 is as follows:

	2019	2018
Expected life in years	10.0	10.0
Risk-free interest rate	2.44%	2.52%
Expected volatility	120%	121%
Forfeiture rate	—	—
Dividend yield	—%	—%
Weighted-average fair value of options granted	0.75	1.03

9. LEASED PROPERTIES

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018 and terminates on July 31, 2021. The Company has the option to extend the term of the lease for one year.

Microchips, which the Company acquired in November 2019, leases general office space in Lexington, Massachusetts and warehouse space in Billerica, Massachusetts. The Lexington lease commenced on July 1, 2013 and terminates on September 30, 2021. The Billerica lease commenced on October 1, 2016 and terminates on March 31, 2022.

Under the terms of each lease, the Company pays base annual rent (subject to an annual fixed percentage increase), plus property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and

measuring lease liabilities. The leases do not require material variable lease payments, residual value guarantees or restrictive covenants.

The leases do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company used an incremental borrowing rate of 7% as of January 1, 2019 for the operating leases that commenced prior to that date. The depreciable lives of operating lease assets and leasehold improvements are limited by the expected lease term.

At December 31, 2019, the Company reported operating lease right of use assets of approximately $488,000 in other non-current assets, and approximately $411,000 and $389,000, respectively, in current and non-current other liabilities on the consolidated balance sheet.

Total operating lease costs were approximately $223,000 for the year ended December 31, 2019. Operating lease costs consist of monthly lease payments expense, common area maintenance and other repair and maintenance costs and are included in general and administrative expenses in the consolidated statement of operations.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $154,000 for the year ended December 31, 2019, and these amounts are included in operating activities in the consolidated statement of cash flows. Further, at December 31, 2019, operating leases had a weighted average remaining lease term of 1.89 years.

At December 31, 2019, future minimum lease payments under the Company's operating leases are as follows:

Year ending December 31,		
2020	$	461,000
2021		363,000
2022		42,000
Total future minimum lease payments		866,000
Less: accreted interest		(66,000)
Total operating lease liabilities	$	800,000

10. COMMITMENTS AND CONTINGENCIES

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.

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 Collaborations

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene.

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.

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.

SST License and Collaboration Agreement

In February 2018, the Company entered into a license and collaboration agreement with Strategic Science & Technologies-D, LLC and Strategic Science & Technologies, LLC, referred to collectively as SST, under which the Company received 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, the Licensed Product, which is defined as SST's topical formulation of Sildenafil Cream, 3.6% as it existed as of the effective date of the 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.

The following is a summary of other terms of this license and collaboration 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 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 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 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.

Orbis Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Orbis Biosciences, or Orbis, for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). Under this agreement, the Company paid Orbis $300,000 to conduct the first stage of development work, Stage 1, as follows: $150,000 upon signing the agreement, $75,000 at the 50% completion point, not later than 6 months following the date the 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 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 agreement provides the Company with an option to enter into a license agreement for ORB-204 and ORB-214 should development efforts be successful.

Catalent JNP License Agreement

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc. (formerly known as Juniper Pharmaceuticals, Inc., and which the Company refers to as Catalent), under which Catalent granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, 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 Catalent 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 this agreement.

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

Annual Maintenance Fee. The Company will pay an annual license maintenance fee to Catalent on each anniversary of the date of the 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 Catalent 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 agreement.

Royalty Payments. During the royalty term, the Company will pay Catalent mid-single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, the Company will pay Catalent a low double-digit percentage of all sublicense income the Company receives for the sublicense of rights under the agreement to a third party.

Pear Tree Acquisition

In May 2018, the Company completed its acquisition of Pear Tree Pharmaceuticals, Inc., or Pear Tree. 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.

Under the merger agreement that governed the acquisition, the Pear Tree former stockholders and their representatives, or 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.

Hammock/MilanaPharm Assignment and License Agreement

In December 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. In December 2019, the Company entered into amendments to each of the Assignment Agreement and License Amendment.

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

License Fees. The Company paid MilanaPharm: (1) $25,000 in connection with the execution of the License Amendment; (2) $100,000 on December 5, 2019; and (3) $110,000 on January 31, 2020.

Milestone Payments. The Company 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. 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, 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, as amended:

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 Hammock: (1) $250,000 in connection with the execution of the Assignment Agreement; (2) $125,000 on December 5, 2019; and (3) 137,500 on January 31, 2020.

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 milestone payments.

Microchips Acquisition

On November 20, 2019, the Company completed its acquisition of Microchips Biotech, Inc., or Microchips, pursuant to the Agreement and Plan of Merger, dated as of November 10, 2019. On the closing date of the merger, Microchips became a wholly owned subsidiary of the Company. The Company acquired Microchips to secure the rights to develop user-controlled, long-acting reversible contraception.

The Company issued an aggregate of 2,999,990 shares of its common stock to the holders of shares of Microchips' capital stock outstanding immediately prior to the effective time of the merger. The Company also agreed to pay the following contingent consideration: (a) up to $46.5 million contingent upon the achievement of specified funding, product development and regulatory milestones (b) up to $55.0 million contingent upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property acquired by Daré in the merger; (c) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. The Company agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to the implantable contraceptive product in development by Microchips. The Company expects approximately $1.0 million of the contingent consideration payments to become payable through 2021.

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 approximately $96,000 and $53,000 during the years ended December 31, 2019 and 2018, respectively.

11. GRANT AWARDS

Eunice Kennedy Shriver National Institute of Child Health and Human Development

During 2018 and 2019, the Company received grant funding for clinical development efforts supporting Ovaprene 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 NIH issues notices of awards to the Company for a specified amount, and the Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment. If the Company receives payments under the award, the amounts of such 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.

As of December 31, 2019, the Company received award payments totaling $1.2 million, approximately $0.2 million of which was received in 2018 and approximately $1.0 million of which was received in 2019. The remaining portion of the award under the grant, approximately $700,000, is contingent upon, among other matters, assessment of the results of the ongoing post-coital test trial of Ovaprene to satisfy specified requirements set out in the award notice, and the availability of funds. The Company recorded credits to research and development expense for costs related to the NIH award of $1.2 million and $225,000 for the years ended December 31, 2019 and December 31, 2018, respectively.

Bill & Melinda Gates Foundation

Microchips has a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation, relating to the development of Microchips' contraceptive program. Expenses eligible for grant funding must be incurred, tracked and reported to the Foundation. In July 2019, Microchips received approximately $2.9 million in grant funding payments. At December 31, 2019, grant funding payments associated with research and development expenses for Microchips' contraceptive program not yet incurred totaled approximately $2.0 million and are recorded as deferred grant funding liability in the Company's consolidated balance sheet.

12. SUBSEQUENT EVENTS

ATM Sales

Between January and March 2020, the Company sold an aggregate of 3,308,003 shares of common stock in "at-the-market" equity offerings and received aggregate gross proceeds of approximately $5.4 million and incurred sales agent commissions and fees of approximately $204,000 (see Note 7).

Exercise of February 2018 Warrants

In January 2020, warrants to purchase an aggregate of 1.7 million shares of common stock were exercised at an exercise price of $0.98 per share resulting in gross proceeds to the Company of approximately $1.7 million (see Note 7).

Bayer HealthCare License Agreement

On January 10, 2020, the Company entered into a license agreement with Bayer HealthCare LLC, or Bayer, regarding the further development and commercialization of Ovaprene in the U.S. Under the agreement, the Company received a $1.0 million upfront payment from Bayer. If Bayer pays an additional $20.0 million to the Company (the "Clinical Trial and Manufacturing Activities Fee"), after Bayer receives and reviews the results of the pivotal clinical trial of Ovaprene, which payment Bayer may elect to make in its sole discretion, the license grant to Bayer to develop and commercialize Ovaprene for human contraception in the U.S. becomes effective. Such license would be exclusive with regard to commercialization and co-exclusive with the Company with regard to development.

Under the agreement, the Company would also be entitled to receive (a) a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S. and escalating milestone payments based on annual net sales of Ovaprene during a calendar year, totaling up to $310.0 million if all such milestones, including the first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Under the agreement, the Company will be responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer will support the Company in development and regulatory activities by providing up to two full-time equivalents with expertise in clinical, regulatory, preclinical, commercial, CMC and product supply matters in an advisory capacity. After payment of the Clinical Trial and Manufacturing Activities Fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of (a) the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S.; or (b) 15 years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days days notice and the agreement will automatically terminate if the Company does not receive the Clinical Trial and Manufacturing Activities Fee if and when due.

COVID-19

In response to the spread of COVID-19, in March 2020 we implemented work-from-home and restricted travel policies and, subsequently, the governors of California and Massachusetts, where we have operations, issued statewide stay-at-home orders. While we have systems and technologies in place to enable our employees to work from home, productivity may be adversely impacted and challenge our ability to effectively manage and operate our business. In addition, many of our consultants, partners and vendors on which we rely heavily are subject to similar work and travel restrictions that may adversely impact their ability to perform contracted services in a timely manner or at all. The effect of the COVID-19 pandemic and its associated restrictions may increase the anticipated aggregate costs for the development of our product candidates and may adversely impact our anticipated timelines for the development of our product candidates by, among other things, causing disruptions in the supply chain for our clinical supplies, delays in the timing and pace of subject enrollment in our clinical trials and lower than anticipated subject enrollment and completion rates, delays in the review and approval of our regulatory submissions by the FDA and other agencies with respect to our product candidates, and other unforeseen disruptions. The economic impact of the COVID-19 pandemic and its adverse effect on capital markets and investor sentiment may adversely impact our ability to raise capital when needed or on terms favorable to us and our stockholders to fund our development programs and our operations. We do not yet know the full extent of potential delays or impacts on our business, clinical trial activities, ability to access capital or on healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our business and financial condition.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 27, 2020, Daré Bioscience, Inc. (the "Company," "we," "our" and "us") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act"): common stock, $0.0001 par value per share ("common stock").

General

The following is a brief description of the rights of our common stock. The description is qualified in its entirety by reference to, and should be read in conjunction with, our Restated Certificate of Incorporation (as amended, "Certificate"), our Second Amended and Restated By-laws (as amended, "Bylaws"), and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). Our Certificate and Bylaws are filed as exhibits to the Annual Report on Form 10-K of which this exhibit is a part. The Annual Report is filed with the U.S. Securities and Exchange Commission and is publicly available. We encourage you to read our Certificate, our Bylaws and the applicable provisions of the DGCL for additional information.

Authorized Capital

We are authorized to issue up to 120,000,000 shares of common stock and up to 5,000,000 shares of preferred stock, $0.01 par value per share (the "preferred stock"). As of March 27, 2020, no shares of preferred stock are outstanding.

The issued and outstanding shares of common stock are duly authorized, validly issued, fully paid and nonassessable.

Rights of Holders of our Common Stock

Dividend Rights. Subject to preferences that may apply to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Voting Rights. Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights.

Liquidation Rights. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

No Preemptive Rights. Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock.

Rights of Preferred Stock May be Senior to Rights of Common Stock. Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the holders of our common stock.

Anti-Takeover Effect Provisions

Certain provisions in our Certificate and in our Bylaws may have an anti-takeover effect, including:

Classified Board. We have a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the composition of a majority of our board of directors.

Number of Directors. The number of directors on our board of directors is established by our board of directors, which may delay the ability of stockholders to change the composition of a majority of our board of directors.

No Cumulative Voting. Our stockholders cannot cumulate their votes in the election of directors, which limits the ability of minority stockholders to elect director candidates.

Filling of Vacancies. Our board of directors have the exclusive right to elect a director to fill any vacancy or newly created directorship.

Removing Directors. A director may be removed only for cause and only by the affirmative vote of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.

Prohibition on Written Consent. Our stockholders are prohibited from acting by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders.

Calling Special Meetings. Special meetings of our stockholders may be called only by our board of directors, the chairman of our board of directors or our chief executive officer, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors.

Advance Notice Procedures. Stockholders must comply with the advance notice procedures in our Bylaws to nominate candidates to our board of directors and to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from soliciting proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us;

Supermajority Provisions. The affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors is required to amend or repeal, or to adopt any provision inconsistent with, the provisions in our Certificate that relate to, among other matters, the classification of our board of directors, the number of our directors, the removal of our directors, the filling of vacancies on our board of directors, the prohibition on our stockholders to act by written consent, and the calling of special meetings of our stockholders.

Bylaw Amendments. Our board of directors, by majority vote, may amend, alter or repeal our Bylaws and may adopt new Bylaws. Our stockholders may not adopt, amend, alter or repeal our Bylaws or adopt any provision inconsistent therewith, unless such action is approved, in addition to any vote required by our Certificate, by the affirmative vote of holders of at least 75% of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors, and the affirmative vote of holders of at least 75% of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors is required to amend or repeal, or to adopt any provision inconsistent with, the foregoing. These provisions may inhibit the ability of an acquirer from amending our Certificate or our Bylaws to facilitate a hostile acquisition and may allow our board of directors to take additional actions to prevent a hostile acquisition.

Preferred Stock. Our board of directors can determine to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could significantly dilute the ownership of a hostile acquirer.

Additional Authorized Shares of Capital Stock. The shares of authorized common stock and preferred stock available for issuance under our Certificate could be issued at such times, under such circumstances, and with such terms as to impede a change in control.

In addition, we are subject to Section 203 of the DGCL, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any "business combination" with any "interested stockholder" for

three years following the date that such stockholder became an interested stockholder, unless: (i) before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (a) by persons who are directors and also officers and (b) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock not owned by the interested stockholder.

The term "business combination" generally includes mergers or consolidations resulting in a financial benefit to the interested stockholder. The term "interested stockholder" generally means any person, other than the corporation and any direct or indirect majority-owned subsidiary of the corporation, who, together with affiliates and associates, owns (or owned within three years prior to the determination of interested stockholder status) 15% or more of the outstanding voting stock of the corporation.

Exclusive Forum

Our Bylaws provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee, agent or stockholder of the Company to the Company or the Company's stockholders, including, without limitation, a claim alleging the aiding and abetting of such a breach of fiduciary duty, (c) any action asserting a claim arising pursuant to any provision of the DGCL, our Certificate or our Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (d) any action asserting a claim governed by the internal affairs doctrine or other "internal corporate claim" as that term is defined in Section 115 of the DGCL. Our Bylaws also provide that any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock shall be deemed to have notice of and consented to the foregoing.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders have appraisal rights in connection with a merger or consolidation of the Company. Under the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "DARE."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN OMITTED.

License Agreement

This License Agreement ("Agreement"), dated as of 10 January, 2020 ("Execution Date"), is entered into by and between Bayer HealthCare LLC with its principal offices at 100 Bayer Boulevard, Whippany, NJ 07981 ("Bayer") and Daré Bioscience, Inc., with its principal office at 3655 Nobel Drive, Suite 260, San Diego, CA 92122 ("Daré"). Throughout this Agreement Bayer and Daré are each referred to as a Party and together as the Parties.

WITNESSETH:

WHEREAS, Daré is developing a monthly, non-hormonal, vaginal ring known as Ovaprene;

WHEREAS, Bayer has expertise in the development and commercialization of human pharmaceutical products and devices, and desires to obtain an exclusive license for the development and commercialization of the Product (as defined below) in the United States;

WHEREAS, the Parties have agreed to enter into this Agreement for the purpose of granting Bayer the exclusive license to commercialize the Product in the United States on the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, the PARTIES hereto agree as follows.

ARTICLE 1: DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or the plural, except as expressly set forth herein, shall have the following meanings:

1.1 "Affiliate" means any business entity controlled by, controlling or under common control with a Party at the Execution Date or at any time during the Term and as long as such control remains. For the purpose of this definition, a business entity shall be deemed to "control" another business entity if it:

1.1.1 owns directly or indirectly more than fifty percent (50%) of the outstanding voting securities, capital stock or other comparable equity or ownership interest of such business entity having the power to vote on or direct the affairs of such business entity, as applicable (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), or

1.1.2 possesses, directly or indirectly, the power to direct or cause the direction of the policies and management of such business entity, as applicable, whether by the ownership of stock, by contract or otherwise.

1.2 "ATI" means ADVA-Tec, Inc.

1.3 "Bayer Mark" means any Mark other than the Licensed Mark, which Mark is Controlled by Bayer and which Bayer uses in connection with the Commercialization of the Product.

1.4 "Clinical Trial and Manufacturing Activities Fee" means the amount of Twenty Million Dollars (USD $20,000,000.00).

1.5 "Commercialize" or "Commercialization" means all activities undertaken relating to use for commercial purposes, including pre-marketing, marketing, distribution, sale, offering for sale, sampling, securing market access, pricing, medical affairs support and educational activities.

1.6 "Commercialization Condition" means that: (a) Bayer notifies Daré of Bayer's intention to pay the Clinical Trial and Manufacturing Activities Fee pursuant to Section 2.2; (b) the agreement relating to the supply of Product described in Section 8.1 is concluded prior to the expiration of the [***] period described in Section 2.1 (as such period may be extended in accordance therewith); and (c) Daré has received the Clinical Trial and Manufacturing Activities Fee from Bayer, all in accordance with the process and timelines set forth in Article 2.

1.7 "Commercialization Date" means the date that the Commercialization Condition is performed.

1.8 "Commercially Reasonable Efforts" means the level of effort, budget and resources normally used by a Party for a product owned or controlled by it, which is of similar projected profitability and at a similar stage in its development or product life, taking into account with respect to a product any issues of patent coverage, safety and efficacy, product profile, the proprietary position of the product, the then-current competitive environment for the product and the likely timing of the product(s) entry into the market, the regulatory environment of the product and other relevant scientific, technical, economic and commercial factors.

1.9 "Confidential Information" has the meaning set forth in Section 11.1 below.

1.10 "Control" means, with respect to any material, information, or other intellectual property right, that a Party (a) owns or has a license to such material, information, or other intellectual property right and (b) has the ability to grant to the other Party access, a license or a sublicense (as applicable) to such material, information, or other intellectual property right as provided for herein without (i) requiring the consent of a Third Party, (ii) incurring cost to a Third Party (other than royalties or other revenue share requirements contemplated pursuant to a license agreement), or (iii) violating the terms of any agreement or other arrangement with any Third Party.

1.11 "Daré License" means that certain License Agreement entered into by and between Daré and ATI effective July 19th, 2017.

1.12 "Develop" or "Development" means to engage in research and development activities (including preclinical studies, clinical trials, CMC development and regulatory activities).

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

1.14 "Field" means human contraception.

1.15 "First Commercial Sale" means the first commercial sale of a Product by Bayer or an Affiliate or sublicensee of Bayer to a person or entity who is not Bayer or an Affiliate or sublicensee of Bayer in the Territory after grant of a Marketing Approval. For the avoidance of doubt, supply of Product as samples or to patients for compassionate use, named patient use, clinical trials or other similar development purposes shall not be considered a First Commercial Sale.

1.16 "Indirect Tax" means any sales, use, value added taxes, excise taxes or other similar taxes, duties, or charges (but excluding taxes on income or similar taxes) that may be imposed by any taxing authority within the Territory.

1.17 "Know How" means all know-how, including all proprietary and confidential commercial, technical, scientific and other information, inventions (whether patentable or not), trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases whether in written, electronic or any other tangible form, including information related to materials, samples, assays, compounds, compositions or formulations. For the avoidance of doubt, any individual piece of Know How ceases to be covered by this definition once it has been publicly disclosed or if any of the exclusions set forth in Section 11.2 apply.

1.18 "Laws" means all applicable laws (including anti-corruption Laws), statutes, rules, regulations (including cGCP, cGLP and cGMP), orders, judgments and/or ordinances of any Regulatory Authority or court having effect from time to time in the Territory.

1.19 "Licensed Know How" means any Know How Controlled by Daré or any of its Affiliates as of the Execution Date or at any time during the Term, that is necessary to Commercialize the Product or that is useful exclusively in relation to Commercializing the Product, in each case, within the Field. Know-How that is owned or controlled by an entity that becomes an Affiliate of Daré after the Execution Date and that is not used by Daré in the development or commercialization of the Product shall not constitute Licensed Know How.

1.20 "Licensed Mark" means any Mark Controlled by Daré or any of its Affiliates, as of the Execution Date or at any time during the Term within the Territory, specifically related to the Product, including Ovaprene. Marks that are owned or controlled by an entity that becomes an Affiliate of Daré after the Execution Date and that are not used by Daré in the development or commercialization of the Product in the Field and Territory shall not constitute Licensed Marks.

1.21 "Licensed Patent Rights" means any of the following:

1.21.1 the Patent Rights listed in Exhibit 1.21 hereto, and

1.21.2 any Patent Rights Controlled by Daré or any of its Affiliates as of the Execution Date or at any time during the Term that are necessary to Commercialize the Product or that are useful exclusively in relation to Commercializing the Product, in each case in the Field (and Patent Rights that are owned or controlled by an entity that becomes an Affiliate of Daré after the Execution Date and that are not used by Daré in the development or commercialization of the Product shall not constitute Licensed Patent Rights).

1.22 "Licensed Technology" means the Licensed Patent Rights and Licensed Know How.

1.23 "Manufacture" and "Manufacturing" means all operations required to manufacture, test, release, handle, package, store and destroy a Product.

1.24 "Mark" means any word, name, symbol, color, designation or device or any combination thereof for use in the course of trade, including all trademarks, service marks, brand mark, trade dress,

logos, slogans, designs, brand names, trade names, business symbols, domain names, social media handles, and all other indicia of origin, together with all translations, adaptations, derivations, and combinations thereof, and all registrations, applications for registration thereof and social media handles associated therewith, together with any extensions and renewals thereof and all goodwill associated therewith.

1.25 "Marketing Approval" means any approval, license, registration or authorization, including a Premarket Approval, required from the relevant Regulatory Authority to market and sell the Product in the Territory.

1.26 "Net Sales" means the aggregate gross invoiced sales prices from the sale of Products sold by Bayer and its Affiliates and sublicensees, less the following deductions, actually incurred, paid or accrued by Bayer or its Affiliate or sublicensee: (i) normal trade, quantity and cash discounts, rebates, or similar payments actually granted or given to wholesalers or other distributors, buying groups, health care insurance carriers, managed care entities or other institutions, including any government-mandated rebates; (ii) returns, rejections or recalls (due to spoilage, damage, expiration of useful life or otherwise); (iii) reasonable freight, packing, shipping and postage charges; and (iv) customs or excise taxes on the sale of a Product required by Laws, including import duties, value added, sales and use tax and other taxes (except income taxes) or duties relating to importation, use or sales of a Product. In the event of any sale or other disposal for value, such as barter or counter-trade, of a Product, other than an arms'-length transaction for cash, Net Sales shall be calculated as above based on the value of the non-cash consideration received or the fair market price of such Product in the country of sale or disposal. In no event shall any particular amount of deduction identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions). All discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated between Products and other products of Bayer and its Affiliates and sublicensees bundled or sold with such Products such that the Product does not bear a disproportionate portion of such deductions.

1.27 "Patent Challenge" has the meaning contained in Section 12.8.

1.28 "Patent Rights" mean:

1.28.1 all national, regional and international patents, patent applications, utility models, design patents and design rights filed in any country of the world including provisional patent applications;

1.28.2 all patents, patent applications, utility models, design patents and design rights filed either from such patents, patent applications, utility models, design patents, design rights or provisional patent applications or claiming priority from either of these, including any continuation, continuation-in part, division, provisional, converted provisional and continued prosecution applications, or any substitute application;

1.28.3 any patent issued with respect to or in the future issued from any such patent applications;

1.28.4 any and all extensions or restorations by existing or future extension or restoration mechanisms, including reissues, re-examinations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents, patent applications, utility models, design patents and design rights; and

1.28.5 any foreign counterparts of the foregoing.

1.29 "Pivotal Trial" means the pivotal clinical trial or trials to be conducted in the US for the purpose of obtaining Premarket Approval of the Product known as Ovaprene.

1.30 "PMI" means Poly-Med, Inc.

1.31 "Premarket Approval" or "PMA" means a premarket approval application filed with the FDA, for approval by such agency for the marketing and sale of Products in the US pursuant to 21 CFR 814, as such regulations may be amended from time to time.

1.32 "Product" means the monthly, non-absorbable silicone-based, non-hormonal (which releases ferrous gluconate and ascorbic acid), ring-based vaginal contraceptive device, wherein the ringed-mesh comprises a composite ring comprising a flexible matrix containing one or more bioactive agent or agents and needed excipients or modulators, which encircles a fluid-permeable mesh material, currently known as Ovaprene. Product shall include any improvement or modification to the Product that is made or introduced by or on behalf of either Party during the Term; provided that Bayer shall acquire no rights to any improvement or modification to the Product that is not Controlled by Daré.

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

1.34 "Regulatory Authority" means the FDA or any national or local agency, authority, department, inspectorate, official, or public or statutory person having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.35 "Regulatory Documentation" means all applications, registrations, licenses, authorizations and approvals, all correspondence 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, in each case specifically addressing the Product, and all data included in the foregoing, including all IDEs, PMAs, Marketing Approvals, adverse events files and complaints files.

1.36 "Results Package" has the meaning stated in Section 2.1.

1.37 "Side Letter" means that letter sent by PMI to Daré dated March 18, 2017 in which PMI agrees with Daré certain undertakings in the event of a breach of the Daré License or the insolvency of ATI.

1.38 "Sublicense Revenue" means all cash payments, the fair market cash value of any equity consideration (less any amounts paid for such equity consideration), and forgivable loans (to the extent actually forgiven) received by Bayer or its Affiliates in consideration for and directly attributable to the grant of a sublicense hereunder, including without limitation upfront payments, license maintenance fees, royalties, milestone payments or the like, subject to the following provisions:

1.38.1 Where Bayer receives a royalty from a sublicensee based on such sublicensee's Net Sales, if such royalty is equal to or less than the royalty payable by Bayer under Section 9.3 for the same Net Sales, then such royalty is excluded from Sublicense Revenue. Where Bayer receives a royalty from a sublicensee based on such sublicensee's Net Sales, if such royalty is greater than the royalty payable by Bayer under Section 9.3 for the same Net Sales, then the difference between the royalty payable by Bayer under Section 9.3 for such Net Sales and the royalty received by Bayer from such sublicensee for such Net Sales shall constitute Sublicense Revenue.

1.38.2 Where Bayer receives a payment from a sublicensee based on such sublicensee's achievement of a milestone set forth in Section 9.2, if such payment is equal to or less than the payment payable by Bayer under Section 9.2 for achievement of the same milestone, then such payment is excluded from Sublicense Revenue. Where Bayer receives a payment from a sublicensee based on such sublicensee's achievement of a milestone set forth in Section 9.2, if such payment is greater than the amount payable by Bayer under Section 9.2 for achievement of the same milestone, then the difference between the amount payable by Bayer under Section 9.2 for such milestone and the amount received by Bayer from such sublicensee for such milestone shall constitute Sublicense Revenue. For the avoidance of doubt, milestone payments received from a sublicensee that do not correspond to the milestones identified in Section 9.2 constitute Sublicense Revenue.

1.38.3 Any payments received by Bayer from a sublicensee for equity in Bayer or its Affiliates in consideration for and directly attributable to the grant of a sublicense hereunder shall be deemed to be Sublicense Revenue to the extent that the sublicensee's payments for such equity exceeds the fair market value of such equity on the date the obligation to make such payments are received by Bayer.

1.39 "Term" shall have the meaning stated in Section 12.1.

1.40 "Territory" means the United States of America, including Puerto Rico and the U.S. Virgin Islands.

1.41 "Third Party" means any entity or person other than Bayer or Daré or their respective Affiliates.

1.42 "Valid Claim" means a claim of any issued and unexpired patent or patent application within the Licensed Patent Rights that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (b) has not been revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) is not lost through an interference proceeding. Notwithstanding the foregoing, if a claim of a pending patent application within the Licensed Patent Rights in the United States has not issued as a claim of a patent within the five (5) years after the PCT filing date from which such claim takes priority (or the first national filing date if no PCT was filed), such claim shall not be a Valid Claim for the purposes of this Agreement, unless and until such claim issues as a claim of an issued patent (from and after which time the same shall be deemed a Valid Claim subject to the foregoing clauses (a) through (d) above).

ARTICLE 2: DEVELOPMENT PHASE

2.1 Results Package. Daré will promptly (at least within [***] days) notify Bayer in writing when the database containing results of the Pivotal Trial is locked. Daré shall provide to Bayer a copy of all

tables, listings and figures (TLFs) in SAS or other agreed upon format and the key results memo that Daré delivers to its senior management (together, "Results Package") within [***] days after the date that Daré delivers the said memo to its senior management. The Results Package shall include the results of any Human Factor Engineering study activities that Daré has performed. Bayer may request a copy of the database from the Pivotal Trial in a mutually agreed upon format for review. Bayer shall notify Daré within [***] days of receiving the Results Package if it wishes to pay the Clinical Trial and Manufacturing Activities Fee, provided that Bayer may request in writing additional background information and data to clarify the contents of the Results Package, which information and data, if available, Daré shall promptly make available to Bayer to the extent that such requests are commercially reasonable and do not require Daré to generate new data, and the said [***] day period shall be extended by the period it takes for Daré to provide the reasonably requested information and data if such period exceeds [***] days. For clarity, the database will be "locked" when a data quality control audit has been completed and all data has been entered, cleaned, and quality control-checked for the trial.

2.2 Clinical Trial and Manufacturing Activities Fee. Bayer may, in its sole and absolute discretion, pay and reimburse Daré for costs and expenses incurred and to be incurred by or on behalf of Daré and its Affiliates in support of conducting clinical trials and product manufacturing activities, and supporting services in furtherance of the development and manufacture of the Product, by paying the Clinical Trial and Manufacturing Activities Fee. The Clinical Trial and Manufacturing Activities Fee shall be paid only if (a) Bayer serves notice of its intention to pay the Clinical Trial and Manufacturing Activities Fee in accordance with the timeline stated in Section 2.1, and (b) the agreement relating to the supply of Product as described in Section 8.1 is concluded. Following fulfillment of both conditions, Daré shall issue an invoice for the Clinical Trial and Manufacturing Activities Fee and the amount invoiced shall be paid within [***] days of receipt of the said invoice. For clarity Bayer is not liable or responsible for any costs and expenses relating to the Pivotal Trial or any other clinical trial or manufacturing activities or services that Daré may undertake or obtain and Bayer's total liability for any such activities and services is the Clinical Trial and Manufacturing Activities Fee, payment of which is entirely within Bayer's discretion irrespective of the quality, quantity or extent of activities and services Daré may undertake and obtain. If this Agreement is terminated prior to payment of the Clinical Trial and Manufacturing Activities Fee for any reason, Bayer shall not be liable for payment of any costs or expenses incurred by or on behalf of Daré either before or after such termination in connection with the Pivotal Trial or any other trial, study or activity.

2.3 Diligence. From the Execution Date to fulfillment of the Commercialization Condition, Bayer shall have the right to undertake additional due diligence, and Daré shall respond in a timely manner to any reasonable requests made by Bayer, with respect to its evaluation of the Product. Without prejudice to the generality of the foregoing, Bayer may request to review FDA correspondence including meeting minutes and IDE submissions, protocols and reports of preclinical studies, and CMC documents including Quality Control specifications. In addition, Bayer may request to conduct audits at any relevant manufacturing sites including but not limited to those of ATI and PMI, and to request to perform investigator site visits at selected sites relating to the Pivotal Trial and review data, provided that appropriate patient and site consents exist, and as permissible according to applicable Law, including those laws relating to patient privacy, in which case Daré will use commercially reasonable efforts to seek requisite consents and approvals.

ARTICLE 3: PIVOTAL TRIAL

3.1 Daré shall, at its own cost and expense, carry out the Pivotal Trial. Daré shall be solely responsible, at its sole cost and expense, for the conduct of the Pivotal Trial, which shall be conducted in a

manner as agreed with the FDA. Any changes to the protocol or other aspects of the Pivotal Trial shall be made only following notice to Bayer of the proposed change. Such notice will be given in sufficient time in advance of the implementation of the change to allow Bayer to properly consider the change and to discuss it with Daré. Daré agrees to take reasonable account of any reasonable suggestions or objections made by Bayer, recognizing that the data to be generated will be used by Bayer to make an informed decision on whether to perform the Commercialization Condition.

ARTICLE 4: LICENSE GRANT

4.1 License Grant by Daré. Commencing upon the Commercialization Date and subject to the terms of this Agreement, Daré grants to Bayer a royalty-bearing, irrevocable (but terminable pursuant to Article 12: license (including the right to grant sublicenses pursuant to Section 4.2 below) under Daré's interest in the Licensed Technology to Develop and Commercialize the Product, where the manufacture, use, sale or import of the Product is covered by the Licensed Technology, in the Field in the Territory. Such license shall be exclusive with regard to Commercialization and co-exclusive with Daré with regard to Development.

4.2 Sublicensing. Subject to the terms of this Agreement, Bayer may sublicense (but with no right to grant further sublicenses) the rights granted to Bayer under Section 4.1 to any Bayer Affiliate or Third Party.

4.2.1 Bayer Responsibility. Any sublicense granted by Bayer hereunder shall not relieve Bayer from any of its obligations under the Agreement and Bayer will be responsible for all actions of its sublicensee in connection with such sublicense.

4.2.2 Consent of Daré. Any sublicense to a Third Party shall require the prior written consent of Daré, such consent not to be unreasonably withheld, delayed or conditioned. In considering the reasonableness of withholding any such consent, it is acknowledged that Daré has selected Bayer as a licensee hereunder due to its expertise and presence in the Field and in the Territory, including its capacity and resource to successfully Commercialize the Product. It is intended by Daré that any non-Affiliate sublicensee should have expertise, presence, capacity and resource in the Field in the Territory that is comparable to Bayer's.

4.2.3 Requirements. Each sublicense shall be in writing and consistent with and subject to the terms and conditions of this Agreement, including granting Daré and its licensors the audit rights stated in Article 10. Bayer shall provide Daré a copy of each sublicense agreement, and each amendment thereto or extension thereof (redacted as appropriate regarding information on products unrelated to the Product and unrelated to the Licensed Technology), within [***] days of execution, and Bayer acknowledges that Daré may disclose such copies to its licensors as necessary. All sublicenses granted by Bayer shall terminate automatically and immediately upon expiration or termination of this Agreement. Bayer shall terminate a sublicense if the sublicensee commits any action or omits to take any action that would constitute a material breach of this Agreement if committed by Bayer, and if such sublicensee fails to cure such action or omission within the corresponding cure period provided in this Agreement.

4.3 Retained Rights. Daré and its licensors shall have and retain the rights to use the Licensed Technology to further Develop the Product in the Territory, and shall retain all rights to Develop

and Commercialize the Product outside the Territory, and to Develop and Commercialize the Product outside the Field.

4.4 [***].

ARTICLE 5: DEVELOPMENT / REGULATORY

5.1 Responsibility. Subject to the terms and conditions of the Agreement, Daré shall be solely responsible, at its sole cost and expense, for the Development of, and all regulatory activities in connection with, the Product(s) in the Field in the Territory.

5.2 Efforts. Daré shall use Commercially Reasonable Efforts to Develop the Product, including development and establishment of commercial manufacturing on a suitable scale, and completing the Pivotal Trial.

5.3 Reporting. Daré shall provide to Bayer quarterly update reports about the progress of its efforts to Develop the Product, including the Pivotal Trial, and interactions with Regulatory Authorities. Such reports shall be in sufficient detail to enable a meaningful review by Bayer and assessment on whether Daré's diligence obligations are being fulfilled and Development is progressing. At Bayer's request Daré shall, from time to time, provide Bayer with access to the Regulatory Documentation (which constitutes Daré's Confidential Information). As a minimum the reports on the Pivotal Trial shall contain details of recruitment status, drop outs, pregnancies and SAEs.

5.4 Regulatory Submissions and Approvals. Daré shall be solely responsible for filing for and shall own (or its designees shall own) all IDEs and PMAs, and any other regulatory approvals relating to the Development of Product.

5.5 Subsequent Development. The Parties shall discuss and seek to align on Development activities intended to support lifecycle management of the Product following the Commercialization Date.

5.6 Alliance Management. As soon as possible following the Execution Date the Parties shall each nominate an alliance manager to facilitate the exchange of information on the Pivotal Trial and Bayer's ongoing due diligence as described in Section 2.3.

5.7 Bayer Support. Bayer shall support Daré in the conduct of the Pivotal Trial and other Development activities by providing up to two (2) full time equivalents with expertise in clinical, regulatory, preclinical, commercial, CMC and product supply matters in an advisory capacity. Additionally, Bayer will provide Daré with new product commercialization input on commercially relevant clinical trial endpoints consistent with Bayer's current reasonable and customary practices. Bayer shall provide Daré with such cooperation and assistance as may reasonably be requested with respect to Regulatory Approvals and interactions and communications with Regulatory Authorities in respect of Products within the Territory.

ARTICLE 6: COMMERCIALIZATION

6.1 Responsibility. Subject to the terms and conditions of the Agreement, following the Commercialization Date, Bayer shall be solely responsible, at its sole cost and expense, for the Commercialization of the Product in the Field in the Territory, and shall do so in accordance with all Laws.

6.2 Efforts. Following the Commercialization Date, Bayer shall use Commercially Reasonable Efforts to Commercialize the Product in the Territory. Bayer shall establish and consistently seek to achieve specific and meaningful sales goals and allocate sufficient resources designed to meet its business objectives for the Product, including, but not limited to, fielding, training (including any reasonably necessary medical education) and supervising a sales force (including an appropriate management structure) reasonably necessary for Bayer to perform its commercialization obligations hereunder. Without limiting the foregoing:

6.2.1 Not later than [***] days prior to the expected First Commercial Sale, Bayer shall prepare and submit a marketing plan to Daré for the Product ("Marketing Plan") for Daré's information, which plan will provide a three-year budget, market assessment, strategic drivers, pricing, and a reasonably detailed summary of operating strategies and tactics, advertising, marketing and educational materials, and sales and marketing promotional materials and activities intended to promote and support sales of the Product in the Territory, including the aggregate number of projected detailing calls. The Marketing Plan will be updated by Bayer and on an annual three-year rolling basis, which update shall be submitted to Daré for its information not later than [***] days in advance of the first day of the next applicable calendar year. The Marketing Plan shall be Bayer's Confidential Information.

6.2.2 For each calendar year following Regulatory Approval, Bayer shall provide to Daré within [***] days after the end of such calendar year a written report that summarizes the Commercialization activities performed by or on behalf of Bayer and its Affiliates and sublicensees during such calendar year, including information supporting its obligations under this Section 6.2.

6.2.3 Bayer or its Affiliate or sublicensee will effect a First Commercial Sale within [***] days of Regulatory Approval; provided that (i) no delay is caused by circumstances beyond the reasonable control of Bayer, and that (ii) sufficient Product has been supplied by or on behalf of Daré unless and until a Direct Supply occurs.

6.3 Cooperation of Daré. Subject to any duties and restrictions owed under applicable Law and/or to Third Parties, following the Commercialization Date, Daré shall fully cooperate with and provide assistance to Bayer in connection with any pricing and reimbursement filings or any other filing with a Regulatory Authority or payer, in each case with respect to the Product, including by executing any required documents, providing access to personnel and providing all such documentation as Bayer may reasonably require, including the Regulatory Documentation.

6.4 Regulatory Submissions and Approvals. Daré shall be responsible for filing for and shall own (or its designees shall own) all Marketing Approvals and any other regulatory approvals relating to the Commercialization of the Product in the Territory. Daré shall provide to Bayer a copy of all written substantive communications from and with any Regulatory Authority involving a regulatory submission for the Product or any other component thereof sufficiently in advance, where feasible, to enable Bayer to have a meaningful opportunity to provide input on the content of such submission and, if reasonably requested by Bayer, to participate in scientific advice meetings with the Regulatory Authority related to the Product. At Bayer's request Daré shall provide Bayer with access to the Regulatory Documentation.

6.5 Medical Affairs. Following the Commercialization Date, Bayer shall be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding the Product in the Field in the Territory. If Daré receives questions about the

Product in the Territory after the Commercialization Date, it shall refer such questions to Bayer, and Bayer shall be responsible for responding thereto.

6.6 Anti-Diversion. Bayer will not, and will ensure that its Affiliates and sublicensees will not, actively promote, market, solicit, distribute, import, sell or have sold Products, including via the Internet or mail order, to any Third Party, address or Internet Protocol address outside the Territory. If Bayer or an Affiliate or sublicensee receives any order from a prospective purchaser located outside the Territory for Product that is intended for use or sale outside the Territory, it shall promptly refer that order to Daré and shall, to the extent permitted by applicable Laws, not accept such order.

ARTICLE 7: PHARMACOVIGILANCE

7.1 Exchange of Information. Both Parties agree to promptly exchange relevant information that relates to the safety of the Product and to comply with all applicable laws and regulations relating to the Product concerning Product safety.

7.2 Pharmacovigilance Agreement. In furtherance of Section 7.1, the Parties shall negotiate a pharmacovigilance agreement diligently and in good faith with the goal of executing such agreement no later than [***] days from fulfillment of the Commercialization Condition. As Marketing Authorization Holder, Daré shall create and maintain a master safety database and shall be the sole owner of such database. Bayer shall submit to Daré all data collected by it with respect to Adverse Events relating to the Product in accordance with the timelines and subject to the conditions set forth in the said pharmacovigilance agreement.

ARTICLE 8: SUPPLY AND MANUFACTURING

8.1 Supply of Product. Commencing upon the Execution Date, the Parties shall negotiate a supply agreement diligently and in good faith with the goal of executing such agreement no later than [***] days from [***]. Such supply agreement will provide that, after the Commercialization Date, Daré [***] will supply Bayer, and Bayer will purchase from Daré [***], all of Bayer´s requirements of packaged and labelled Product. Such agreement shall contain provisions consistent with the terms set forth in Exhibit 8.1 attached hereto, and shall include as an annex a Quality Agreement containing terms and conditions regarding quality assurance/quality control and compliance with applicable standards, laws and regulations. [***].

8.2 Product Price. Following the Commercialization Date and ending upon [***], Daré shall supply Product to Bayer at a price [***]. If such unit cost exceeds the maximum price specified below in this Section 8.2, Bayer will pay such excess, and such excess will be credited against the milestone and royalty payments due by Bayer hereunder. It is not the intent of the Parties that milestone and royalty payments be unreasonably and significantly reduced or eliminated by the foregoing provision, and if Daré considers that the milestones and royalties payable to it hereunder will be unreasonably reduced in any particular year as a result of the requirement to credit the aforementioned excess, without affecting Daré's obligation to pay the excess, Bayer agrees to discuss with Daré in good faith to avoid such a significant reduction in any particular year..

Period	Maximum Price (US Dollars)
From the Commercialization Date until [***]	[***]
[***] – [***]	[***]
[***] and thereafter	[***]

Notwithstanding the foregoing, the per-unit cost of Manufacture of the Product may increase by [***] per annum, commencing on the [***] following First Commercial Sale, to accommodate for inflation. The cost of Manufacture of the Product will be more particularly defined in the supply agreement referred to in Section 8.1.

8.3 The supply agreement referred to in Section 8.1 shall contain provisions that will [***], and will [***]; provided, however, that [***]. For clarity, the Parties intend that said provisions shall be [***] in the supply agreement referred to in Section 8.1.

ARTICLE 9: FINANCIAL PROVISIONS

9.1 Up Front License Fee. In consideration of the license granted by Daré to Bayer hereunder, Bayer shall pay to Daré a non-refundable up front license fee of one million US Dollars ($1,000,000) within thirty (30) days of the Execution Date. Daré shall issue an invoice for this fee at Bayer's request.

9.2 Milestone Payments. The payments set forth in this Section 9.2 shall be paid upon the first achievement of the applicable milestone event below. Within [***] days following achievement of each milestone, Bayer shall notify Daré of the occurrence of such milestone, and Daré shall issue an invoice for the relevant amount. Bayer shall pay Daré the following amounts as applicable:

Milestone Event	Amount
First Commercial Sale	$[***]
Annual Net Sales reaching $[***]	$[***]
Annual Net Sales reaching $[***]	$[***]
Annual Net Sales reaching $[***]	$[***]
Annual Net Sales reaching $[***]	$[***]

The Net Sales stated above are calculated by reference to sales within a specific calendar year and are not cumulative. No milestone payments shall be made more than once, and no amounts shall be due for subsequent or repeated achievements of any milestone(s). No additional milestone payments shall be due in respect of any follow-on Product, or Product with different characteristics to a Product for which a milestone payment was made.

9.3 Royalties.

9.3.1 Royalty Rate. During the term of this Agreement Bayer will pay Daré royalties on annual Net Sales during each calendar year, at the following rates:

Annual Net Sales in US Dollars	Royalty Rate
$[***] – [***]	[***]%
$[***] – [***]	[***]%
$[***] – [***]	[***]%

Above $[***]	[***]%

provided, however, that upon the expiration of (1) the last to expire Valid Claim within the Licensed Patent Rights covering the manufacture, use, sale and import of the Product in the Territory; or (2) the last to expire marketing, data or similar exclusivity for the Product conferred by a Regulatory Authority that provides an exclusive commercialization period during which Bayer, its Affiliates or its sublicensees have the exclusive right to market and sell the Product in any region in the Territory (excluding any rights conferred by or based on any Licensed Patent Rights); whichever is later, each royalty rate set forth above shall be reduced by [***] percent ([***]%).

9.3.2 Royalties not Cumulative. In determining the applicable royalty rate, the Net Sales stated above are not cumulative and the relevant royalty rate will be calculated on a calendar year-by-calendar year basis.

9.3.3 Blended Rates. With respect to the royalty rates for the Product, the Parties acknowledge and agree that the Licensed Patent Rights and Licensed Know-How licensed pursuant to this Agreement justify royalty rates of differing amounts with respect to sales of the Product, which rates could be applied separately to the Product involving the exercise of such Licensed Patent Rights and/or the use or incorporation of such Licensed Know-How, and that if such royalties were calculated separately, royalties relating to Licensed Patent Rights and royalties relating to Licensed Know-How would last for different terms. The Parties have determined in light of such considerations and for reasons of convenience that blended royalty rates for the Patent Rights and the Know-How licensed hereunder will apply during the Term (which blended royalty rates would be advantageous to both Parties), subject to the royalty reduction calculation set forth in Section 9.3.1. Consequently, the Parties have agreed to adopt the royalty rates set forth in this Section 9.3.

9.3.4 Royalty Stacking. If during the Term Bayer becomes aware of a Third Party Patent Right and where Bayer reasonably determines, in the absence of a license to such Third Party Patent Right, such Third Party Patent Right would be infringed by Bayer's Commercialization of the Product in the Field and in the Territory as permitted herein, Bayer (itself or through any other Bayer Affiliate) may obtain a license to such Third Party Patent Right in the Territory. In the event that Bayer pays royalties to such Third Party for the acquisition of a license to such Third Party Patent Rights, Bayer shall deduct from the royalty payable by Bayer to Daré pursuant to this Section 9.3 in a given calendar quarter all royalties paid to such Third Party in such quarter under such agreement, provided that in no event shall Bayer reduce the royalties payable to Daré hereunder by more than [***] percent ([***]%) of the royalties otherwise payable. Royalties payable in respect of Net Sales made by a Bayer sublicensee may be reduced by operation of this Section 9.3.4 only where the operative Third Party license agreement is entered into by Bayer and such Third Party.

9.3.5 Quarterly Royalty Reporting and Royalty Payment. All royalty payments shall be made at quarterly intervals. Within [***] days of the end of each quarter after the First Commercial Sale of the Product, Bayer shall submit a statement which shall show for that quarter: (i) Net Sales, (ii) a calculation of the royalty payment due on such Net Sales, (iii) offsets made pursuant to Section 9.3.4, and (iv) such other relevant details as Daré may reasonably

request. Without limiting Bayer's obligations under this Section 9.3.5, Daré shall issue invoices for royalties at Bayer's request.

9.4 Sublicense Revenue. Bayer shall pay Daré [***] percent ([***]%) of all Sublicense Revenue. All Sublicense Revenue shall be made at quarterly intervals. Within [***] days of the end of each quarter following the first grant of a sublicense, Bayer shall submit a statement which shall show for that quarter: (i) all outstanding sublicenses; (ii) Sublicense Revenue, (iii) a calculation of the amount payable to Daré under this Section 9.4, and (iv) such other relevant details as Daré may reasonably request. Without limiting Bayer's obligations under this Section 9.4, Daré shall issue invoices for such amounts at Bayer's request.

9.5 Payments.

9.5.1 Currency. Bayer shall make the payments due to Daré under the Agreement in US Dollars.

9.5.2 Payment Rule. All payments shall be made by Bayer within thirty (30) days of the date of receipt of invoice. Daré shall issue invoices for the Up Front License Fee and Clinical Trials and Manufacturing Activities Fee at Bayer's request.

9.5.3 Invoice Address. All invoices to Bayer shall be sent to the following address:

Bayer HealthCare Pharmaceuticals [***]

Alternatively, each invoice for payments may be sent electronically in portable document format (pdf) via email without electronic signature ("pdf-invoicing"), thus replacing a corresponding paper form.

9.5.4 Payments Made by Wire Transfer. All payments made by Bayer to Daré under the Agreement shall be made by wire transfer to the following bank account of Daré, or such other bank account as notified by Daré to Bayer at least fifteen (15) business days prior to the due date of the next payment:

For domestic transfers:

Account Holder:	[***]
Account Number:	[***]
Bank Code:	[***]
Routing and Transfer:	[***]

For international transfers:

Account Holder:	[***]
Account Number:	[***]
Pay to:	[***]
SWIFT (BIC):	[***]
Routing and Transit:	[***]

9.5.5 Late Payments. Any payment due to Daré by Bayer under this Agreement that is not paid within thirty (30) days after it is due will accrue interest on a daily basis at a rate of 1.5%

per month (or the maximum legal interest rate allowed by applicable law, if less) from and after such date.

9.5.6 Taxes. Both Parties agree to comply with all tax laws and regulations in effect during the Term and applicable to this Agreement. All agreed consideration in respect to any supply or service rendered by any of the Parties under this Agreement is exclusive of Indirect Taxes. Bayer will promptly pay all such separately stated, invoiced taxes and duties, unless Bayer provides Daré a valid, signed exemption certificate or direct pay permit, as appropriate. If tax is not charged by Daré and applicable tax law subsequently determines tax to be due, then Bayer will pay all such applicable taxes as identified either by reimbursing Daré as invoiced or directly paying taxing authority. If it is determined through change of law that taxes have been paid by Bayer to Daré in error, then Daré shall credit Bayer for such paid taxes according to the terms of this Agreement (and if there is credit outstanding as of the date of expiration or termination of this Agreement then Daré shall pay Bayer the amount of such credit within sixty (60) days of expiration or termination).

9.6 No Other Compensation. Neither Party will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other hereunder, except as otherwise expressly set forth herein. No amounts paid are refundable or creditable.

ARTICLE 10: BOOKS, RECORDS, AUDIT

Bayer and its Affiliates and sublicensees shall maintain complete and accurate records which are relevant to the calculation of Sublicense Revenue and of royalties payable by Bayer to Daré on Net Sales of Products under this Agreement, and such records shall be open during reasonable business hours for a period of [***] years from creation of individual records for examination at Daré's expense and not more often than [***] each calendar year, and on thirty (30) days' prior notice, by an independent certified public accountant selected by Daré or its licensor and reasonably acceptable to Bayer for the sole purpose of verifying for Daré the correctness of calculations of Sublicense Revenue and royalties and classifications of Net Sales under this Agreement. Daré shall bear its and its licensor's own costs related to such audit; provided, that for any underpayments by Bayer of royalties and/or Sublicense Revenue to Daré in a calendar year that is identified based on such audit that are greater than [***] percent ([***]%), Bayer shall pay Daré interest as provided for in Section 9.5.5 from the time the underpaid amount was due and Daré's or its licensor's out-of-pocket expenses for the audit. For any underpayments by Bayer found under this Article 10, Bayer shall pay Daré the amount of such underpayment within thirty (30) days of receipt of an invoice therefor. Any overpayments by Bayer will, at Bayer's option, be refunded to Bayer or credited to future royalties. Any records or accounting information received from Bayer shall be Bayer's Confidential Information, and the accountant will sign a confidentiality agreement in form and substance that is reasonably satisfactory to Bayer prior to beginning the audit. Results of any such audit shall be provided to both Parties and shall also be deemed Confidential Information for purposes of Section 11.1.

ARTICLE 11: CONFIDENTIALITY

11.1 As used herein, "Confidential Information" means all confidential or proprietary information disclosed by one Party or its Affiliates ("Disclosing Party") to the other Party or its Affiliates ("Receiving Party") pursuant to the Agreement. Confidential Information may be conveyed in written, graphical, physical, electronic or oral form. Licensed Know How constitutes Daré's Confidential Information.

11.2 Confidential Information does not include information that:

11.2.1 at the time of disclosure, is in the public domain;

11.2.2 after disclosure, becomes part of the public domain, except by breach of the Agreement by the Receiving Party;

11.2.3 the Receiving Party can establish was in its possession and at its free disposal at the time of disclosure by the Disclosing Party, as shown by the Receiving Party's records kept in the ordinary course of its business;

11.2.4 the Receiving Party rightfully obtains from a Third Party; provided that such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party under an obligation of confidentiality; and

11.2.5 is developed by or for the Receiving Party independently and without use of the Confidential Information provided by the Disclosing Party, as shown by the Receiving Party's records kept in the ordinary course of its business.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the Receiving Party unless the combination itself are published or known to the general public or are in the rightful possession of the Receiving Party.

11.3 Obligation of Confidentiality and Non-Use. Each Party agrees that:

11.3.1 it shall hold in confidence and take such steps as it normally takes to protect its own confidential and proprietary information, but in any event no less than reasonable steps, to preserve the confidentiality of the Confidential Information disclosed to it by the Disclosing Party under the Agreement;

11.3.2 it shall not use the Confidential Information of the Disclosing Party for any purposes other than to perform the Receiving Party's obligations or exercise the Receiving Party's rights under the Agreement, without first entering into a written agreement signed by both Parties covering such other use thereof; and

11.3.3 it shall not to disclose Confidential Information other than as permitted by Sections 11.4 or 11.5.

11.4 Permitted Disclosures. Notwithstanding the obligations of confidentiality and non-use set forth in Section 11.3, a Receiving Party may provide Confidential Information disclosed to it:

11.4.1 to its officers, directors and employees who have a need to know such information in furtherance of the purpose of this Agreement and are bound by an obligation of confidentiality (contractual, legal, fiduciary or otherwise) and non-use at least as restrictive as set forth herein;

11.4.2 to its Affiliates, sublicensees, prospective sublicensees, and their officers, directors and employees, who have a need to know such information in furtherance of the purpose of this Agreement and are bound by an obligation of confidentiality (contractual, legal, fiduciary or otherwise) and non-use at least as restrictive as set forth herein;

11.4.3 to any actual or potential distributors, co-promoters or co-marketers who in each case have a need to know such information in furtherance of the Receiving Party's performance of this Agreement are bound by a contractual obligation of confidentiality and non-use at least as restrictive as set forth herein;

11.4.4 to Regulatory Authorities as necessary to obtain, maintain or defend Patent Rights or seek or obtain approval to conduct clinical trials, or gain Marketing Approval with respect to a Product.

The Receiving Party shall be liable and responsible for the aforementioned persons' and entities' compliance with the provisions of this Article 11.

11.5 Required Disclosures. Notwithstanding the obligations of confidentiality and non-use set forth in Section 11.3, a Receiving Party may provide Confidential Information disclosed to it if such disclosure is required by (i) Law, (ii) Securities Exchange Rules, or (iii) a validly issued subpoena, order of a court of competent jurisdiction or other request for information from a Regulatory Authority; provided that prior to any such disclosure, to the extent permitted by Law, the Receiving Party required to make the disclosure shall promptly notify the Disclosing Party of such requirement. Such Disclosing Party shall have a reasonable opportunity to review and comment on the proposed disclosure and/or seek a protective order or other appropriate remedy. The Receiving Party required to make the disclosure shall consider in good faith the comments provided by the Disclosing Party and shall furnish only that portion of the Confidential Information that the Receiving Party is legally required to furnish. Confidential Information disclosed pursuant to this Section shall remain Confidential Information for all other purposes of the Agreement.

11.6 Duration. The Receiving Party's obligation under the Agreement to preserve the confidentiality of any and all of the Confidential Information disclosed to it by the Disclosing Party shall continue during the Term and for a period of ten (10) years after any termination or expiration of the Agreement (except that such obligations shall survive indefinitely thereafter with respect to Confidential Information that is treated by the Disclosing Party as a trade secret for so long as such Confidential Information is a trade secret according to applicable Law).

11.7 Publicity. Bayer and Daré will, upon their written agreement, issue a press release announcing the execution of the Agreement as agreed between the Parties. Except with respect to such initial press release or as otherwise required by Laws (including disclosure requirements of any stock exchange on which securities issued by a Party are traded), neither Party shall issue an additional press release or public announcement relating to this Agreement or any of the activities hereunder without the prior written approval of the other Party, which shall not be unreasonably withheld or delayed. Notwithstanding the above, each Party and its Affiliates may disclose on its website and in its promotional materials that the other Party is a development and/or commercialization partner of such Party for the Product and may use the other Party's name and logo in conjunction with such disclosure.

ARTICLE 12: TERM AND TERMINATION

12.1 Term. This Agreement shall commence on the Execution Date and shall continue in full force and effect, unless otherwise terminated pursuant to this Article 12, until the later of (i) expiration of any Valid Claim covering the manufacture, use, sale or import of the Product in the Territory; or (ii) fifteen (15) years from First Commercial Sale ("Term"). The Term shall be automatically renewed for subsequent 12-month renewal terms unless either Party notifies the other Party of non-renewal within ninety (90) days of expiration of the then-current initial term or renewal term (as applicable),

in which case this Agreement shall terminate upon expiration of the then-current initial term or renewal term (as applicable).

12.2 Automatic Termination. This Agreement will automatically terminate, without requirement of any action taken by either Party, if the Commercialization Condition is not fulfilled as described in Section 1.6.

12.3 Unilateral Right to Terminate Agreement. Bayer may terminate this Agreement without cause at any time on serving on Daré ninety (90) days' notice of termination.

12.4 Termination by Daré. Daré may, upon notice to Bayer, terminate this Agreement (i) in the event of a Patent Challenge as described in Section 12.8 below; (ii) if Force Majeure prevents Bayer from performing its obligations under this Agreement for [***] or longer; or (iii) for Bayer's violation of Export Control Laws as set forth in Section 19.15.

12.5 Termination for Breach. Either Party may terminate this Agreement, effective immediately following written notice to the other Party, for any material breach by the other Party of any term of this Agreement that remains uncured ninety (90) days after the non-breaching Party first gives written notice to the other Party of such breach and its intent to terminate this Agreement if such breach is not cured. If the breach is not capable of being cured within such ninety (90) days period and provided the breaching Party reasonably demonstrates that it is exerting good faith efforts to cure the breach, the period for cure will be extended for a period of no more than one hundred and eighty (180) days. For purposes of clarity, the obligation of the breaching Party to cure any such breach shall be stayed for any time period during which such breach is the subject of a dispute resolution proceeding pursuant to Article 18; provided that the obligation of the breaching Party to cure such breach shall resume commencing on the date of any final resolution of such proceeding.

12.6 Termination for Insolvency. In the event that either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within one hundred twenty (120) days of the filing thereof, and provided than none of the foregoing is being done as part of a corporate reorganization, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

12.7 Termination for Safety Reasons. In the event that Bayer makes a good faith determination in accordance with its standard practices and procedures for such determinations that there is a material safety issue with respect to the Product, then Bayer may terminate this Agreement upon thirty (30) days' notice.

12.8 Patent Challenge. If Bayer or an Affiliate or sublicensee (a) commences or voluntarily participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of any Licensed Patent Rights, or (b) voluntarily assists any Third Party in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of any Licensed Patent Rights (each of (a) and (b), a "Patent Challenge"), then, to the extent permitted by applicable Law, Daré shall have the right, in its sole discretion, to terminate this Agreement upon notice to Bayer. Notwithstanding the foregoing, if the Patent Challenge is made by an Affiliate of Bayer and no person within Bayer's legal department had actual knowledge of such Patent Challenge, and no Bayer personnel directly involved in Ovaprene had actual knowledge of such Patent Challenge, then Daré may not terminate this Agreement unless it notifies Bayer of such Patent Challenge and

the Affiliate does not withdraw or cause to be withdrawn such challenge within ninety (90) days of receipt of such notice, in which case Daré shall have the right to terminate this Agreement by providing written notice thereof to Bayer. The foregoing right to terminate shall not apply with respect to any Patent Challenge where the Patent Challenge is made in defense of an assertion of the relevant Patent Right that is first brought by Daré against Bayer.

12.9 Consequences of Termination of Agreement. In the event of the termination of this Agreement, the following provisions shall apply, as applicable:

12.9.1 If this Agreement is terminated by Bayer pursuant to Section 12.3 or Section 12.7:

(a) All licenses and rights granted by Daré to Bayer, including all licenses granted to Bayer pursuant to Section 4.1, shall immediately terminate.

(b) Bayer shall cease to use any Marketing Approval obtained in accordance with the Agreement.

(c) Bayer shall cease to conduct any activity related to the Development and/or Commercialization of the Product.

(d) Each Party shall promptly return all Confidential Information of the other Party that are not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

(e) Bayer shall, and shall cause its Affiliates and sublicensees, to provide reasonable assistance, at no cost to Daré, as may be reasonably necessary or useful for Daré or its designee to commence or continue commercializing Products in the Territory and to generally effect a smooth and orderly transition of commercialization activities with respect to the Product, for a period of up to one hundred eighty (180) days after the effective date of termination (the "Transition Period"), including transferring or amending as appropriate, upon request of Daré, any agreements or arrangements with Third Parties to commercialize the Products in the Territory, and domain names as described in Section 16.7.8. To the extent that any such contract between Bayer or its Affiliate or sublicensee and a Third Party is not assignable to Daré or its designee, then, to the extent reasonably practicable, Bayer shall reasonably cooperate with Daré (but without Bayer retaining any liability under such contract or incurring expense or cost to the Third Party) to arrange to continue to and provide such services from such entity.

(f) Bayer and its Affiliates and sublicensees shall: (A) transfer or assign, or cause to be transferred or assigned, to Daré or its designee (or to the extent transfer or assignment is not permitted by Law, take all reasonable actions to make available to Daré or its designee) the full benefits (including the right of reference, to the extent consistent with Law) of all Regulatory Applications, Regulatory Approvals, Regulatory Materials, regulatory dossiers, applications for Pricing Approval, and Pricing Approvals, for the Product, all as existing at the date of termination whether held in the name of Bayer or its Affiliate; (B) provide to Daré or its designee originals of all of the foregoing documents, as well as copies of all correspondence with relevant Regulatory Authorities or Pricing Authorities

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

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

(h) Bayer shall, if requested by Daré, deliver to Daré all Promotional Materials in Bayer's and its Affiliates' and sublicensees' possession (including electronic files of all Promotional Materials), and Daré will reimburse Bayer for its out-of-pocket cost for printing and delivering such materials. Notwithstanding the foregoing, Daré shall retain no rights to use the Bayer name or the Bayer cross following termination of this Agreement.

(i) To the extent permissible by Law Bayer and its Affiliates and sublicensees shall transfer to Daré any and all data exclusivity rights for the Product as existing at the date of termination, including regulatory or statutory exclusivity periods.

(j) Subject to any obligations of confidentiality owed to Third Parties and to the extent they relate specifically to the Product, Bayer shall promptly provide to Daré a list of all agreements in effect between Bayer and its Affiliates and sublicensees on the one hand, and any distributors on the other hand, of Products in the Territory, including the identity of and contact information for each such Third Party, and will use Commercially Reasonable Efforts to facilitate introductions between Daré and such Third Parties, and Bayer will disclose copies of such agreements to Daré to the extent permitted by the relevant Third Party (either through the agreement itself, or through the Third Party's written consent). Bayer shall use Commercially Reasonable Efforts to include in each such agreement a provision allowing it to assign such agreement to Daré in the event of termination of this Agreement.

(k) Each Party shall promptly return all Confidential Information of the other Party that is not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

12.9.2 If this Agreement is terminated by either Party on any grounds except by Bayer pursuant to Section 12.3:

(a) All licenses and rights granted by Daré to Bayer, including all licenses granted to Bayer pursuant to Section 4.1, shall immediately terminate;

(b) Bayer shall cease to use any Marketing Approval obtained in accordance with the Agreement;

(c) Bayer shall cease to conduct any activity related to the Development and/or Commercialization of the Product;

(d) Each Party shall promptly return all Confidential Information of the other Party that is not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder

(e) Bayer and its Affiliates and sublicensees shall: (A) transfer or assign, or cause to be transferred or assigned, to Daré or its designee (or to the extent transfer or assignment is not permitted by Law, take all reasonable actions to make available to Daré or its designee) the full benefits (including the right of reference, to the extent consistent with Law) of all Regulatory Applications, Regulatory Approvals, Regulatory Materials, regulatory dossiers, applications for Pricing Approval, and Pricing Approvals, for the Product, all as existing at the date of termination whether held in the name of Bayer or its Affiliate; (B) provide to Daré or its designee originals of all of the foregoing documents, as well as copies of all correspondence with relevant Regulatory Authorities or Pricing Authorities pertaining to Products; and (C) take such other reasonable actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section to Daré or its designee, at Daré's cost and expense. Notwithstanding the above, if Bayer cannot complete (A) through (C) as set forth above due to Law or contracts that prohibit the same, Bayer will take all reasonable actions to make the above available to Daré or Daré's designee, at Daré's cost and expense;

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

(g) Bayer shall, if requested by Daré, deliver to Daré all Promotional Materials in Bayer's and its Affiliates' and sublicensees' possession (including electronic files of all Promotional Materials), and Daré will reimburse Bayer for its out-of-pocket cost for printing and delivering such materials. Daré may use such Promotional Materials solely in connection with the Product as existing at the time of termination and solely in accordance with applicable Law. Notwithstanding the foregoing, Daré shall retain no rights to use the Bayer name or the Bayer cross following termination of this Agreement; and

(h) To the extent permissible by Law Bayer and its Affiliates and sublicensees shall transfer to Daré any and all data exclusivity rights for the Product as existing at the date of termination, including regulatory or statutory exclusivity periods.

12.9.3 Termination on any grounds except Sections 12.3 and 12.7 shall be without prejudice to any other rights or remedies either Party may have in law or equity based on the grounds of termination, which shall be cumulative.

12.9.4 Except where expressly provided for otherwise in the Agreement, termination of the Agreement shall not relieve the Parties hereto of any liability, including any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination or exercise, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of the Agreement nor prejudice any Party's right to obtain performance of any obligation. This Section 12.8 shall survive termination or expiry of the Agreement.

12.10 Surviving Provisions. The provisions of Articles 10, 11, 14, 18 and 19 and Sections 4.4, 7.1, 12.9, 12.10 and 13.3, and Bayer's accrued payment obligations, shall survive any termination or expiration of the Agreement.

ARTICLE 13: REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that as of the Execution Date:

13.1.1 It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation;

13.1.2 It has full corporate right, power and authority to enter into the Agreement and to perform its respective obligations under the Agreement;

13.1.3 It is duly authorized to execute and deliver the Agreement, and the person or persons executing the Agreement on its behalf have been duly authorized to do so by all requisite corporate action; and

13.1.4 The Agreement is legally binding upon it and enforceable in accordance with its terms.

13.2 Representations and Warranties by Daré. Daré hereby represents and warrants to Bayer that as of the Execution Date:

13.2.1 General.

(i) The execution and delivery of the Agreement by Daré, the performance of Daré's obligations hereunder and the licenses granted by Daré pursuant to the Agreement (A) do not conflict with or violate any requirement of any Laws existing as of the Execution Date; and (B) do not conflict with, violate, breach or constitute a default under any contractual obligations of Daré or any of its Affiliates existing as of the Execution Date, including the Daré License;

(ii) The documents delivered or made available by Daré to Bayer in connection with the transaction contemplated by the Agreement (including any minutes of meetings with the FDA and other correspondence exchanged with the agency) do not, to Daré's knowledge, contain any untrue statement of a material fact nor omit to state a material fact necessary in order to make the statements contained therein not misleading; and Daré has not, up through and including the Execution Date, withheld from Bayer any material information in Daré's control concerning the Licensed Technology; and

(iii) Neither Daré nor any employee of Daré, or to Daré's knowledge, subcontractor or employee of a subcontractor which has performed services with respect to the Product has been debarred by the FDA or is the subject of any investigation or proceeding which may result in debarment by the FDA.

13.2.2 Licensed Patent Rights.

(i) Exhibit 1.21 contains a correct and complete list of all Licensed Patent Rights as of the Execution Date. To Daré's knowledge, all of the Licensed Patent Rights issued as of the Execution Date are valid and in full force;

(ii) Daré is the sole and exclusive owner of or Controls all right, title and interest in and to all rights licensed hereunder, and is entitled to grant the licenses specified herein;

(iii) Daré has not previously granted, and will not grant during the Term, any right, license or interest in and to the Licensed Technology in the Field and Territory, or any portion thereof, inconsistent or in conflict with the licenses granted to Bayer herein; and

(iv) As of the Execution Date, there are no pending or, to Daré's knowledge, threatened actions, suits, investigations, claims, judgments or proceedings relating to the Licensed Technology. As of the Execution Date, to Daré's knowledge, Daré is not aware of any issued Third Party Patent Right that is or would be infringed by the Development or Commercialization of a Product as contemplated by this Agreement.

13.2.3 Daré License.

(i) it has provided to Bayer a true, correct and complete copy of the Daré License, as reasonably redacted;

(ii) as of the Execution Date the Daré License is in full force and effect;

(iii) as of the Execution Date, it is not in breach of, nor to its knowledge do any circumstances exist upon which ATI might claim that Daré is in breach of, the Daré License. For the avoidance of doubt, Daré is not relieved of its obligations under this Agreement because compliance with or fulfillment of such obligations may give rise to a breach of the Daré License;

(iv) Daré further covenants and agrees that (a) it will take all commercially reasonable steps necessary to maintain in full force and effect, the Daré License for the term thereof (b) it will not assign (except to an Affiliate or to a Third Party to which this Agreement has been assigned as permitted under Section 19.4), amend, restate, terminate in whole or in part, or otherwise modify the Daré License in any way that materially adversely affects Bayer's rights under this Agreement; (c) it will provide Bayer with notice within a reasonable time upon becoming aware of any claim of a breach by Daré under the Daré License or notice of termination of the Daré License made by either Daré or ATI (or any party acting on behalf of such counterparty); and (d) it will use commercially reasonable efforts to enforce its rights under the Daré License to the extent necessary to maintain Bayer's rights hereunder; and

(v) [***].

13.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, DARÉ MAKES NO REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, AND EXPLICITLY DISCLAIMS ANY REPRESENTATION AND WARRANTY, INCLUDING WITH RESPECT TO ANY ACCURACY, COMPLETENESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, VALIDITY, ENFORCEABILITY OR NON-INFRINGEMENT FOR THE LICENSED PATENT RIGHTS, LICENSED KNOW-HOW, AND THE PRODUCT.

ARTICLE 14: LIABILITY AND INDEMNIFICATION

14.1 Indemnification by Bayer. Bayer shall indemnify, defend and hold harmless Daré and its Affiliates and their respective directors, officers, employees and agents (each a "Daré Indemnitee") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) ("Liability") arising or resulting from a claim, suit or proceeding made or brought by a Third Party against a Daré Indemnitee arising from or occurring as a result of (i) the gross negligence or willful misconduct of a Bayer Indemnitee, or (ii) any breach of the representations and warranties set forth in Section 13.1, or (iii) where the Third Party bringing the claim is Daré's or its Affiliate's licensor, to the extent caused by Bayer's or its Affiliate's or sublicensee's breach of this Agreement, or (iv) the Commercialization of the Product by Bayer or its Affiliates or sublicensees except to the extent such Liability falls within the scope of the indemnification obligations of Daré set forth in Section 14.2.

14.2 Indemnification by Daré. Daré shall indemnify, defend and hold harmless Bayer and its Affiliates and its sublicensees and their respective directors, officers, employees and agents (each a "Bayer Indemnitee") from and against any and all Liability resulting from a claim, suit or proceeding made or brought by a Third Party against a Bayer Indemnitee, arising from or occurring as a result of (i) any breach of the representations and warranties set forth in Sections 13.1 and 13.2, (ii) the gross negligence or willful misconduct of a Daré Indemnitee, or (iii) any Development, Manufacture, use, or Commercialization (both within the Territory and outside) of any Product by Daré or its Affiliates and Third Party licensees and sublicensees (including, without limitation, product liability claims), except to the extent such Liability falls within the scope of the indemnification obligations of Bayer set forth in Section 14.1.

14.3 Procedure. The Party seeking indemnification from a Third Party claim or action pursuant to this Article 14 ("Indemnified Party") shall notify the other Party ("Indemnifying Party") promptly upon becoming aware of such claim or action, and shall permit the Indemnifying Party to control the defense and settlement of such claim or action, and shall provide the Indemnifying Party with full cooperation in such efforts, at the Indemnifying Party's request and expense. The Indemnified Party shall not be permitted to consent to settle or compromise any such claim or action without the Indemnifying Party's prior written consent. If the Indemnifying Party fails or declines to assume the defense of any such claim or action within thirty (30) days after notice thereof, the Indemnified Party may assume the defense of such claim or action at the cost and risk of the Indemnifying Party, and any Third Party Liabilities related thereto shall be conclusively deemed a Third Party Liability of the Indemnifying Party. The indemnification rights of an Indemnified Party contained in this Agreement are in addition to all other rights which such Indemnified Party may have at law or in equity or otherwise. The Indemnified Party may participate in the defense of such claim or action with its own counsel at its own expense. The Indemnifying Party may not consent to any settlement or entry of judgment in any such claim or action that does not unconditionally release the Indemnified Party of all liability, and if Bayer is the Indemnifying Party, it may not consent to any settlement or entry of judgment in such claim or action that adversely affects the Licensed Technology or Daré's or its licensor's interests with respect thereto, or that grants any rights to the Licensed Technology except as permitted in Section 4.2, without the consent of Daré, such consent not to be unreasonably withheld.

14.4 Limitation of Liability. EXCEPT FOR AMOUNTS PAYABLE BY A PARTY PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS UNDER SECTIONS 14.1 AND 14.2, IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, OR LOST PROFITS, LOST REVENUE OR LOST GOODWILL, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE, PROVIDED THAT THIS LIMITATION OF LIABILITY SHALL NOT APPLY (I) TO THE EXTENT THAT IT WOULD BE INVALID BY LAW, AND/OR (II) TO DAMAGES CAUSED BY A MATERIAL BREACH OF ARTICLE 11.

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

Parties acknowledge that insurance and liability provisions appropriate to Daré's supply obligations shall be negotiated as part of the agreement described in Section 8.1.

14.6 Survival. This Article 14 will survive expiry or termination of this Agreement for any reason.

ARTICLE 15: FORCE MAJEURE

15.1 Force Majeure. Except with respect to Bayer's payment obligations, neither Party shall be responsible or liable to the other Party for any failure to perform any of its obligations hereunder, if such failure results from circumstances beyond the reasonable control of such Party, which may include requisition by any government authority, the effect of any statute, ordinance or governmental order or regulation, wars, strikes, lockouts, riots, epidemic, disease, an act of God, civil commotion, fire, earthquake, storm, failure of public utilities, common carriers or supplies, or any other circumstances, whether or not similar to the above causes and whether or not foreseeable ("Force Majeure"). The Parties shall use their Commercially Reasonable Efforts to avoid or remove any such cause and shall resume performance under the Agreement as soon as feasible whenever such cause is removed; provided that the foregoing shall not be construed to require either Party to settle any dispute with any Third Party, to commence, continue or settle any litigation, or to incur any unusual or extraordinary expenses.

15.2 Prompt Notification. The Party affected by the Force Majeure event shall upon its occurrence promptly give written notice to the other Party specifying the nature of the event and its anticipated duration.

ARTICLE 16: INTELLECTUAL PROPERTY

16.1 Licensed Technology. Daré and its licensors shall have sole and exclusive ownership of all right, title and interest in and to any and all Licensed Technology.

16.2 Patent Filing, Prosecution and Maintenance. Subject to this Article 16, Daré and its licensors shall have the sole right and responsibility to prepare and file applications with respect to, and prosecute and maintain, at their cost and expense, and using patent counsel or agents of their choice, all Licensed Patent Rights. Bayer shall cooperate with and assist Daré, at Daré's cost, in all reasonable respects, in connection with Daré's preparation, filing, prosecution and maintenance of Licensed Patent Rights.

16.3 Information and Cooperation. The Parties hereby agree to cooperate with each other in connection with the filing, prosecution and maintenance of the Licensed Patent Rights, including through the prompt execution and delivery of documents and instruments as may reasonably be required in connection therewith. Without limiting the foregoing, Daré shall (a) promptly provide Bayer with copies of all patent applications filed hereunder and other material submissions and correspondence with applicable patent offices, in sufficient time to allow for review and comment by Bayer; (b) provide Bayer and its patent counsel with an opportunity to consult with Daré and its patent counsel regarding the filing and contents of any such application, amendment, submission or response; and (c) take into consideration in good faith the advice and suggestions of Bayer and its patent counsel in connection with such filing. With respect to ATI's patent rights, the foregoing is subordinate to Daré's obligations under the Daré License.

16.4 Interference, Opposition, Reexamination and Reissue.

16.4.1 Notice. Not more than thirty (30) days following the discovery by either Party of any request for, or the filing or declaration of, any interference, opposition, or reexamination proceeding with respect to any Licensed Patent Rights in the Territory, the discovering Party shall notify the other Party of such event.

16.4.2 Decision Not to File; Abandonment. Daré shall notify Bayer in the event Daré decides at any time to abandon or discontinue prosecution of any one or more of the patents or patent applications included in the Licensed Patent Rights in the Territory. Such notification will be given as early as possible and in any event not less than fifteen (15) business days prior to the date on which said patent(s) or patent application(s) will become abandoned. Bayer shall have the option, exercisable upon written notification to Daré, to assume full responsibility for the prosecution of such Licensed Patent Rights, which shall be conducted in the name of Bayer. In the event that Bayer takes over any of the patents or patent applications as provided in this Section 16.4.2, such patent or patent application shall cease to be included in the Licensed Patent Rights.

16.5 Enforcement and Defense.

16.5.1 Notice. In the event either Party becomes aware of any suspected infringement or misappropriation of any Licensed Patent Rights ("Infringement"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "Infringement Notice").

16.5.2 Daré Right to Enforce. As between the Parties, Daré shall have the first right, but not the obligation, to address any such Infringement in the Field and the Territory by taking reasonable steps, which may include the institution of legal proceedings or other actions (each, an "Action"), and to compromise or settle such Action; provided, that, (a) Daré shall keep Bayer reasonably informed about such Action, (b) Bayer shall provide reasonable cooperation to Daré, at Daré's expense, in connection with such Action, (c) Daré shall not take any position with respect to, or compromise or settle, such Action in any way that would be reasonably likely to directly and adversely affect the scope, validity or enforceability of the Licensed Patent Rights in the Territory without prior consultation with Bayer, and (d) if Daré does not intend to prosecute or defend an Infringement, or determines to cease to pursue such an Action, it shall promptly inform Bayer and Section 16.5.3 shall apply. Daré shall incur no liability to Bayer as a consequence of such Action or any unfavorable decision resulting therefrom, including any decision holding any such claim invalid, not infringed or unenforceable. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by Daré.

16.5.3 Bayer Right to Enforce. If (a) Daré informs Bayer that Daré does not intend to prosecute an Action in respect of any Licensed Patent Rights pursuant to Section 16.5.2, within ninety (90) days after the Infringement Notice or such shorter period as may be appropriate in the circumstances, or (b) Daré has not commenced any Action within ninety (90) days after the Infringement Notice or such shorter period as may be appropriate in the circumstances, or (c) Daré determines to cease to pursue any such Action with respect to such Infringement, then, subject to ATI's prior written approval with respect to ATI patent rights, Bayer shall have the right, at its own expense, upon notice to Daré to take appropriate action to address such Infringement, including by initiating its own Action or taking over prosecution of any Action initiated by Daré; provided, that, in such event, (i) Bayer shall keep Daré reasonably informed about such Action and shall consult with Daré before taking any major steps during the conduct of such Action, (ii) Daré shall provide

reasonable cooperation to Bayer in connection with such Action, at Bayer's expense, and (iii) Bayer shall not settle any Action without the prior written consent of Daré, not to be unreasonably withheld. Bayer shall keep Daré reasonably informed about the status and developments in such Action, including considering, in good faith, the input of Daré and its licensors regarding the strategy and handling of the litigation. Bayer shall incur no liability to Daré as a consequence of such Action or any unfavorable decision resulting therefrom, including any decision holding any such claim invalid, not infringed or unenforceable. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by Bayer.

16.5.4 Right to Representation. Each Party shall have the right to participate and be represented by counsel that it selects in any Action instituted under Sections 16.5.2 and 16.5.3 by the other Party. If a Party with the right to initiate an Action to eliminate an Infringement lacks standing to do so and the other Party has standing to initiate such Action, then the Party with the right to initiate an Action may name the other Party as plaintiff in such Action.

16.5.5 Cooperation. In any Action instituted under this Section 16.5, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such Action, the other Party shall join such Action and shall be represented using counsel of its own choice, at the requesting Party's expense. The Party instituting the Action will indemnify and hold harmless the joined Party from all damages, claims, liabilities, costs, fines, penalties, losses and expenses, including reasonable attorneys' fees, incurred in connection with such Action.

16.5.6 Allocation of Proceeds. Any amounts recovered by either Party pursuant to Actions under Sections this Section 16.5 with respect to any Infringement, whether by settlement or judgment, shall, after reimbursing Bayer and Daré for their respective reasonable out-of-pocket expenses incurred in pursuing such Action and obtaining such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses) be retained by or paid to Bayer and treated as Net Sales of the Product affected by the Infringement for purposes of this Agreement, such that Bayer shall pay to Daré the applicable royalty due on such Net Sales pursuant to Section 9.3.

16.6 Defense of Claims.

16.6.1 Notice. In the event that any action, suit or proceeding is brought against either Party or any Affiliate of either Party alleging the infringement of the Patent Rights of a Third Party by reason of or the Development or Commercialization, including the Manufacture, use or sale, of the Product, by or on behalf of Bayer, such Party shall notify the other Party within five (5) business days of the earlier of (a) receipt of service of process in such action, suit or proceeding, or (b) the date such Party becomes aware that such action, suit or proceeding has been instituted.

16.6.2 Prosecution of Infringement Claims in the Territory. If the claim relates to Daré's Development activities (a) Daré shall have the primary right but not the obligation to institute and control such action, suit or proceeding in its own name and at its sole expense, and (b) Bayer shall cooperate with Daré in all reasonable respects in any such action, suit or proceeding. In the event Daré waives its primary right as described in this Section 16.6.2, the Parties may elect, without being obliged, to jointly commence an action, in which case the Parties shall be represented by a counsel jointly chosen by the Parties, shall jointly decide on a course of action, and share equally in the costs and expenses, and in and

in amounts recovered with respect to such action. If the claim relates to Bayer's Commercialization of the Product and is brought only against Bayer Indemnitees, Bayer shall have the sole and exclusive rights, but not the obligation, to defend or control any proceedings at its sole expense, and to the extent that the claim is brought against a Daré Indemnitee, the provisions of Section 14.1 shall apply.

16.6.3 Cooperation. Each Party shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party including all documents filed in any litigation. In no event shall Bayer settle or otherwise resolve any such action, suit or proceeding brought against it or its Affiliates in a manner that grants any rights to the Licensed Technology, without Daré's prior written consent.

16.7 Marks.

16.7.1 Mark License. Daré hereby grants to Bayer, and Bayer hereby accepts from Daré a non-exclusive, non-transferable, non-divisible and royalty-free license under any Licensed Mark to promote, market, distribute, use and sell the Product in Field and the Territory under the terms and conditions of this Agreement. If Bayer decides to use the Licensed Mark for the marketing of the Product Bayer shall then comply with brand usage guidelines provided by Daré to Bayer in its use of the Licensed Marks.

16.7.2 This license shall without further action by the Parties expire automatically upon the expiration or termination of this Agreement. Nothing under this Agreement shall be deemed to give Bayer either during or after the Term any right, title or interest in or to the Licensed Mark other than the license granted in Section 16.7.1. Bayer is not entitled to use the Licensed Mark as an element of its company name, as a special characterization of its business operation or company or in any other manner as a mark to distinguish its business operation. Bayer will not register in its own name any Licensed Marks or the corporate name, or other source identifier containing such Licensed Marks or any word or mark that is confusingly similar to such Licensed Marks. All use of the Licensed Mark and all goodwill and benefit arising from such use will inure to the sole and exclusive benefit of Daré and its licensors. Each Party will cooperate with the other Party in the execution, filing and prosecution of any trademark applications in connection with the Licensed Marks in the Territory. Bayer shall assure at all times that the quality of the Products is of a standard of quality consistent with pharmaceutical industry standards. Bayer shall assure at all times that Products are sourced, manufactured and labelled in accordance with all Laws. Bayer shall place and display the Licensed Marks on and in connection with the Products only in such form and manner as are specifically approved in writing in advance by Daré.

16.7.3 The Parties shall promptly notify each other any actual, alleged or threatened infringement of the Licensed Mark or of any unfair trade practices or similar offences of which the Parties take notice. Daré shall at its own expense, have the first right (but not the obligation) to take all steps, including initiating proceedings, to stop any alleged infringement of the Licensed Mark or to defend the Licensed Mark from any attack, including any invalidity or revocation proceedings. At Daré's request, Bayer shall give Daré all reasonable assistance in respect of any such proceedings, subject to Daré meeting all reasonable costs and expenses incurred by Bayer in giving such assistance. If Daré is not willing or interested in initiating action against an infringer, Daré shall notify Bayer accordingly within a period of twenty (20) business days from knowledge of the infringement and Bayer shall be entitled, but not obligated, to enter an action in its own name based on the

infringement of the Licensed Mark subject to Daré's prior written consent. Daré may only refuse its consent for good cause and will give Bayer all assistance as Bayer may reasonably request in connection with any such action. Any funds recovered by either Party as a result of such action shall be shared between the Parties according to the ratio in which they have borne the burden of such action.

16.7.4 Daré shall defend, indemnify and hold Bayer and its officers, directors and employees harmless from and against any and all claims, demands, loss, damage, liabilities, settlement amounts, costs or expenses whatsoever (including reasonable attorneys' fees and costs) arising from any claim, action or proceeding made or brought against Bayer by a Third Party caused by Bayer's or its Affiliate's or sublicensee's authorized use of the Licensed Mark in the Territory for the purpose hereof and in accordance with the terms of this Agreement, alleging that the Licensed Mark infringes any Third Party's trademark rights. Daré shall have no obligation under this Section 16.7.4 where the infringement is caused by modification of the Licensed Mark or combination of the Licensed Mark with another Mark.

16.7.5 Notwithstanding the grant of rights in the Licensed Marks referred to in Section 16.7.1, Bayer shall not be obliged to use the Licensed Mark in Commercializing the Product. Bayer shall be responsible for the selection, registration and maintenance of any Bayer Marks it believes to be appropriate in the Commercialization of the Product.

16.7.6 Daré recognizes, both while this Agreement is in effect and at any time thereafter, the exclusive ownership by Bayer of any proprietary Bayer name, logotype, Bayer Mark, trademark or trade dress furnished by Bayer (e.g. the name "Bayer" and the "Bayer Cross") for use in connection with the marketing, sale or distribution of the Product in the Territory. Daré shall not, either while this Agreement is in effect, or at any time thereafter, register, use or challenge or assist others to challenge the Bayer Marks, the Bayer name, logotype, trademark and trade dress furnished by Bayer or attempt to obtain any right in or to any such name, logotype, trademarks or trade dress confusingly similar for the marketing of the Product as defined in this Agreement or any other pharmaceutical goods and products, notwithstanding that such goods or products have a different use or are dissimilar to the Product as defined in this Agreement.

16.7.7 Only Bayer will be authorized to initiate at its own discretion legal proceedings against any infringement or threatened infringement of the Bayer Marks in the Territory.

16.7.8 Bayer shall have the right to register, host and maintain the Licensed Mark as domain name under a generic Top Level Domain (gTLD) to be agreed with Daré and under the country code Top Level Domain (ccTLD) ".us" and use them for websites and other internet activities in connection with the commercialization of the Product. Bayer shall also be responsible for the registration, hosting, maintenance and defense of any Domain Names reflecting any Mark other than the Licensed Mark under all generic Top Level Domains (gTLDs) and under all relevant country code Top Level Domains (ccTLD). For the avoidance of doubt Bayer is allowed to register such Domain Names in its own name, to host on its own servers, maintain and defend the Domain Names and use them for websites.

ARTICLE 17: USE OF NAME

Neither Party shall use the trademarks or trade names of the other Party, without the prior written consent of such other Party, except as otherwise provided in this Agreement.

ARTICLE 18: DISPUTE RESOLUTION

If the Parties are unable to resolve a dispute, despite their good faith efforts, either Party may refer the dispute to the CEO of Daré and the Head of the Bayer business unit responsible for the Commercialization of the Product. In the event that no agreement is reached by the said CEO and Head (or other designees) with respect to such dispute within thirty (30) days after its referral to them, either Party may pursue any and all remedies available at law or in equity.

ARTICLE 19: GENERAL PROVISIONS

19.1 Interpretation.

19.1.1 the headings of sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of the Agreement or have any effect on its interpretation or construction.

19.1.2 All references in the Agreement to the singular shall include the plural where applicable.

19.1.3 The use of any gender is applicable to all genders.

19.1.4 Unless otherwise specified, references in the Agreement to any section shall include all subsections and paragraphs in such section, and references in the Agreement to any subsection shall include all paragraphs in such subsection.

19.1.5 Any list or examples following the word "including" shall be interpreted without prejudice to the generality of the preceding words.

19.1.6 All references to days or years in the Agreement shall mean calendar days or years, as the case may be, unless otherwise specified.

19.2 Applicable Law. The Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the Laws of the State of New York without giving effect to any choice or conflict of law provisions; provided, however, the foregoing shall not apply to disputes arising out of or relating to intellectual property which shall be governed by applicable federal laws and/or laws of the State of New York (without regard for principles of conflicts of laws) as they apply to the given situation. The Parties further expressly agree that the exclusive venue for the resolution of any such disputes (including intellectual property) shall be the state and federal courts located in New York, New York or the federal courts located in the Southern District of New York, and that such courts shall have exclusive jurisdiction. The Parties hereby submit themselves to the jurisdiction of such courts for such purposes. EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY LEGALLY AND EFFECTIVELY DO SO, TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING HEREUNDER AND ANY CLAIM OF INCONVENIENT FORUM OF ANY COURT IN THE SOUTHERN DISTRICT OF NEW YORK. The prevailing Party in any dispute is entitled to recover its reasonable attorneys' fees.

19.3 Notices. Any notice, consent, or other formal or legal communication required or permitted by this Agreement shall be in writing and shall be sent (a) by prepaid registered or certified mail, return receipt requested, or (b) by express delivery service by an internationally recognized courier, addressed to the other Party at the address shown below or at such other address for which such Party gives notice hereunder:

If to Daré:

Daré Bioscience, Inc.
3655 Nobel Drive, Suite 260
San Diego, CA 92122
Attention: Sabrina Johnson, CEO

If to Bayer:

Bayer HealthCare LLC
100 Bayer Boulevard
Whippany, NJ 07981
Attention: Legal Department

19.4 Assignment.

19.4.1 Subject to Section 19.4.5 below, this Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, each of which such successors and permitted assigns will be deemed to be a Party hereto for all purposes hereof.

19.4.2 No Party may assign, delegate or otherwise transfer either this Agreement or any of its rights, interests, or obligations hereunder without the prior written consent of the other Party. Any attempted assignment by Bayer or Daré in violation of this Section 19.4.2 shall be null and void and of no legal effect.

19.4.3 Notwithstanding Section 19.4.2, each Party, upon providing the other Party prior written notice, may without the consent of the other Party, (i) assign this Agreement in its entirety, to an Affiliate, or (ii) designate one or more of its Affiliates to perform its obligations hereunder, in each case, so long as the assigning Party is not relieved of any liability hereunder and so long as any such Affiliate remains such Party's Affiliate; provided, however, that such Affiliate assignee(s) provide the other Party with written acknowledgement of and agreement to the assigning Party's obligations under the Agreement that were assigned to it.

19.4.4 Notwithstanding Section 19.4.2, each Party (or its permitted successive assignees or transferees hereunder), upon providing the other Party prior written notice, may without the consent of the other Party, assign or transfer this Agreement as a whole to an entity that acquires all or substantially all of the business or assets of such Party relating to this Agreement, whether by merger, acquisition, operation of law or otherwise, so long as such assignment is a Qualified Assignment.

19.4.5 For the purposes of this Agreement, a "Qualified Assignment" means any assignment that:

(i) is made in compliance with applicable Laws;

(ii) includes the assignee's written acknowledgement of and agreement to all of the assigning Party's obligations under the Agreement;

(iii) is made to an assignee that is, and will be after giving effect to the relevant assignment, able to perform its obligations hereunder;

(iv) is made to an assignee that is not subject at the time of such assignment to any order, decree or petition providing for (i) the winding-up or liquidation of such person, (ii) the appointment of a receiver over the whole or part of the assets of such person or (iii) the bankruptcy or administration of such person;

(v) is not a voidable fraudulent conveyance;

(vi) is made to an assignee that is at the time of such assignment not debarred under 21 U.S.C. §30 or under investigation or threatened to be debarred under 21 U.S.C. §30; and

(vii) will not cause a material increase in taxes, costs or expenses to the non-assigning Party (unless the assigning Party or the assignee has agreed to compensate the non-assigning Party for the same).

19.4.6 Notwithstanding Sections 19.4.2 above, each Party may at any time assign its rights, interests and obligations provided for hereunder to any person by merger with the prior written consent of the other Party.

19.5 Severability. If any provision of the Agreement shall be found to be invalid or otherwise unenforceable in whole or in part, the validity or enforceability of the remainder of the Agreement shall not be affected. Furthermore, the Parties agree that the invalid portion of an unenforceable provision or part thereof shall be superseded by an adequate provision that, to the legally permitted extent, comes closest to what the Parties would have desired at the time of conclusion of the Agreement had they considered the issue concerned.

19.6 Affiliates. Each Party may perform its obligations hereunder personally or through one or more Affiliates, and will remain responsible for the acts and omissions of its Affiliates as if such action or omission were taken by such Party itself. Neither Party shall permit any of its Affiliates to commit any act (including any act of omission) which such Party is prohibited hereunder from committing directly.

19.7 Independent Contractors. Nothing in the Agreement shall create, or be deemed to create, a partnership, joint venture or the relationship of principal and agent or employer and employee between the Parties. Neither Party shall enter into or have authority to enter into any engagement or make any representation or warranty on behalf of the other Party or otherwise bind or oblige the other Party hereto. Each Party agrees to perform under the Agreement solely as independent contractor.

19.8 Waiver. Any term or condition of the Agreement may be waived only by a written instrument executed by the Party waiving the benefit of a right hereunder. The waiver by a Party of any right hereunder shall not be deemed a continuing waiver of such right or of another right hereunder, whether of a similar nature or otherwise.

19.9 Amendments. The Agreement (including the attached exhibit(s)) shall not be amended or otherwise modified without a written document signed by a duly authorized representative of each Party.

19.10 Entire Agreement. The Agreement (including the attached exhibit(s)) contains the entire understanding of the Parties with respect to the subject matter hereof. All other express or implied representations, agreements and understandings with respect to the subject matter hereof, either oral or written, heretofore made are expressly superseded by the Agreement.

19.11 Priorities. In the event of any ambiguity, doubt or conflict emerging herein, the terms and conditions of the Agreement shall take precedence over the terms and conditions of any exhibit, unless the latter makes an explicit reference to the provision of the Agreement that shall be amended.

19.12 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

19.13 Applicability of Section 365(n) of the Bankruptcy Code. In the event either Party becomes a debtor under Title 11 of the U.S. Code, this Agreement shall be deemed to be, for purposes of Section 365(n) of Title 11, or any analogous provisions in any other country or jurisdiction, a license to "Intellectual Property" as defined therein and the other Party and its Affiliates, and each of their successors and assigns as licensees shall have the rights and elections as specified in Section 365(n) of Title 11 of the U.S. Code, or any analogous provisions in any other country or jurisdiction. Without limiting the foregoing, upon termination of this Agreement by a trustee or executor of either Party which has rejected this Agreement pursuant to any non-contractual rights afforded to it by applicable bankruptcy law and/or a U.S. or foreign bankruptcy court or other tribunal of competent jurisdiction, all rights and licenses herein granted to the other Party shall nonetheless continue in full force and effect in accordance with the terms of this Agreement.

19.14 Counterparts; Electronic Delivery. The Agreement may be executed in counterparts, each and every one of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each Party may execute the Agreement by Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF signatures of authorized signatories of the Parties shall be deemed to be original signatures, shall be valid and binding upon the Parties, and, upon delivery, shall constitute due execution of the Agreement, provided that such electronic signing and delivery is confirmed in written paper copy signed by and delivered to each Party promptly following electronic signing and delivery.

19.15 Export Control Laws.

19.15.1 In performing this Agreement, each Party agrees to comply strictly and fully with applicable U.S. export control laws, including the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 et seq.), the Trading With the Enemy Act (50 U.S.C. app. §§ 1 et seq.), the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401 et seq.), International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, and all rules, regulations and executive orders relating to any of the foregoing, including but not limited to the Export Administration Regulations (15 C.F.R. §§ 730 et. seq.), and the regulations administered by the Office of Foreign Assets Controls of the United States Department of the Treasury, and all export controls imposed on Products by any country or organization or nations within whose jurisdiction Bayer operates or does business (collectively, "Export Control Laws"). Bayer will not export or permit exportation of the Product or any related technical data or any direct product of any related technical data, outside of the United States without obtaining any required written permission, license, or approval to do so from the Bureau of Industry and Security of the

U.S. Department of Commerce and/or other appropriate governmental agencies of the United States.

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

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

19.15.4 Each Party will fully cooperate and cause its relevant personnel to cooperate with the other Party in the other Party's review or investigation in relation to an actual or potential violation of any applicable export law or regulation in performance of this Agreement.

19.15.5 Each Party understands and acknowledges that, notwithstanding any provision contained herein,

(i) an intentional violation of this Section 19.15 as applicable to the Product by any either Party shall be deemed a material breach of this Agreement and will entitle the other Party to (i) terminate this Agreement immediately upon notice for cause, and (ii) be indemnified for and held harmless against any and all damages, fines, penalties, disgorgements, settlements, determinations, or claims faced by or imposed on the non-breaching Party or any of its representatives to the extent attributable to the material breach of this Section by the breaching Party or any of its respective directors, officers, employees, consultants, agents, sublicensees, subcontractors, distributors, subdistributors or other representatives' and

(ii) a non-intentional violation of this Section 19.15 as applicable to the Product by either Party shall be deemed a non-material breach of this Agreement. Such a breach may be cured by reporting as soon as practicable the basis of the breach to the regulatory agency responsible for the applicable export control laws. In addition each Party

must thereafter cooperate with said agency during any investigation and with any subsequent fines or remediation imposed by said agency.

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Execution Date.

DARÉ BIOSCIENCE, INC.	BAYER HEALTHCARE LLC
By: /s/ Sabrina Martucci Johnson	By: /s/ Ganesh Kamath
Name: Sabrina Martucci Johnson	Name: Ganesh Kamath
Title: Chief Executive Officer	Title: PH Finance Americas

AMENDMENT NO. 1 TO ASSIGNMENT AGREEMENT

This Amendment No. 1 to Assignment Agreement (this "Amendment No. 1") is entered into as of December 4, 2019 (the "Effective Date") between Daré Bioscience, Inc., ("Daré"), and Hammock Pharmaceuticals, Inc., ("Hammock").

WHEREAS, Daré and Hammock are parties to that Assignment Agreement entered into as of December 5, 2018 (the "Agreement").

WHEREAS, Daré and Hammock desire to amend the Agreement as stated herein.

NOW, THEREFORE, the parties hereto hereby agree as follows:

1. Amendment to the Agreement. As of the Effective Date, Section 3.2 of the Agreement is deleted in its entirety and replaced with the following:

> "Deferred Fee. On or before December 6, 2019, Daré shall pay Hammock in cash One Hundred Twenty Five Thousand Dollars ($125,000). Within two business days after January 31, 2020, (such date, the "Deferred Payment Date"), Daré shall pay Hammock One Hundred Twenty Five Thousand Dollars ($125,000) (the "Deferred Fee") plus an additional payment, in cash, of $12,500. 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 $125,000 by the volume weighted average of the sale price for Daré common stock on its primary trading exchange during the ten trading day period immediately preceding the Deferred Payment 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, pay the cash value thereof based on the volume weight average sale price referred to above."

2. Miscellaneous. Except as specifically provided in this Amendment No. 1, no other amendments, revisions or changes are made to the Agreement. All other terms and conditions of the Agreement remain in full force and effect, except that Section 6.5 of the Agreement shall be deemed to incorporate this Amendment and Section 6.8 of the Agreement shall not apply to this Amendment. This Amendment No. 1 may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Delivery of an executed counterpart of a signature page to this Amendment by facsimile or in electronic format (e.g., "pdf") or by other electronic means shall be effective as delivery of a manually executed counterpart of this Amendment No. 1. This Amendment may not be assigned by any party separate and apart from the Agreement, but otherwise shall be binding and assignable as provided in the Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 1 as of the date first written above.

COMPANY:

Daré Bioscience, Inc.

By: /s/ SABRINA MARTUCCI JOHNSON
Name: Sabrina Martucci Johnson
Title: President and CEO
December 18, 2019

Hammock:

Hammock Pharmaceuticals, Inc.

By: /s/ WILLIAM R. MAICHLE
Name: William R. Maichle
Title: President and CEO

AMENDMENT NO. 2 TO LICENSE AGREEMENT

This Amendment No. 2 to the License Agreement (this "Amendment No. 2") is entered into as of December 3, 2019 (the "Effective Date") between 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"). WHEREAS, Daré and Licensors are parties to that First Amendment to License Agreement entered into as of December 5, 2018 (the "Agreement").

WHEREAS, Daré and Licensors desire to amend the Agreement as stated herein.

NOW, THEREFORE, the parties hereto hereby agree as follows:

1. Amendment to the Agreement. As of the Effective Date, Section 4.2.2 of the 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. In the event Daré elects to pay the Deferred Fee in cash, up to but not exceeding half of the Deferred Fee (up to but not exceeding $100,000) (the "Deferred Fee Balance") may be paid within fifteen (15) days of January 31, 2020. In addition to the Deferred Fee Balance, a penalty charge of ten percent (10%) of the Deferred Fee Balance will also be due within fifteen (15) days of January 31, 2020. For example, if the Deferred Fee Balance is $100,000, a penalty charge of $10,000 will also be payable, such that the total amount due is $110,000. 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. Except as specifically provided in this Amendment No. 1, no other amendments, revisions or changes are made to the Agreement. All other terms and conditions of the Agreement remain in full force and effect. This Amendment No. 1 may be attached to and shall form a part of the Agreement. This Amendment No. 1 may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Delivery of an executed counterpart of a signature page to this Amendment

by facsimile or in electronic format (e.g., "pdf") or by other electronic means shall be effective as delivery of a manually executed counterpart of this Amendment No. 1. This Amendment No. 1 will be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, personal representatives, successors and permitted assigns.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 1 as of the date first written above.

Daré Bioscience, Inc.

By: /s/ SABRINA MARTUCCI JOHNSON

Print Name: Sabrina Martucci Johnson

Title: President and CEO

Date: December 13, 2019

Trilogic Pharma, LLC

By: /s/ JAMES HARWICK

Print Name: James Harwick

Title: CEO

Date: December 11, 2019

MilanaPharm LLC

By: /s/ JAMES HARWICK

Print Name: James Harwick

Title: CEO

Date: December 11, 2019

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
Microchips Biotech, 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) and Form S-8 (No. 333-230802) of our report dated March 27, 2020, 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, 2019 (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, 2019 and 2018.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 27, 2020

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: March 27, 2020

/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: March 27, 2020

/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, 2019 (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: March 27, 2020

/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, 2019 (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: March 27, 2020

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