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

# FORM 10-K

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

**For the fiscal year ended December 31 , 2023**
**OR**

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

**Commission File 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**<br>**San Diego , CA**<br>(Address of Principal Executive Offices) | **92122**<br>(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 an 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 | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | x | Smaller reporting company | x |
| | | Emerging growth company | ☐ |

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. o

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ 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 30, 2023), was approximately $ 77,323,000 based on the closing price of the registrant's common stock as reported on the Nasdaq Capital Market on such date. 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 27, 2024, there were 100,581,900 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 2024 annual meeting of shareholders (the "2024 Proxy Statement") are incorporated by reference into Part III of this Annual

Report on Form 10-K where indicated. The 2024 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, 2023**

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## PART I

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K, in particular ITEM 1. "BUSINESS," 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 revenue, funding and expenses, 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," "pursue," "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 1A, "RISK FACTORS," in this report, and elsewhere in this report. Given these uncertainties, you should not place undue reliance on any forward-looking statement. The following factors are among those that may cause such differences:*

- *Inability to raise additional capital, under favorable terms or at all, to fund our operating needs and continue as a going concern;*
- *The number and scope of product development programs we pursue;*
- *Clinical trial outcomes and results of preclinical development;*
- *Failure to complete development of our product candidates or submit and obtain United States Food and Drug Administration, or FDA, or foreign regulatory authority approval for our product candidates on projected timelines or budgets, or at all;*
- *Challenges and delays in obtaining timely supplies of our product candidates, including their components as well as the finished product, in the quantities needed in accordance with current good manufacturing practices, our specifications and other applicable requirements;*
- *The performance of third parties on which we rely to conduct nonclinical studies and clinical trials of our product candidates;*
- *Our failure, or a failure of a strategic collaborator, to successfully commercialize our product candidates, if approved, or our failure to otherwise monetize our portfolio programs and assets;*
- *The timing and amount of future royalty and milestone payments to us, if any, under our out-license agreements for commercialization of XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO, and Ovaprene®;*
- *Termination by a collaborator of our respective out-license agreements for commercialization of XACIATO and Ovaprene, or, in the case of Ovaprene, a decision by the collaborator not to make the license grant fully effective following its review of the results of the ongoing pivotal clinical trial of Ovaprene;*
- *The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;*
- *Difficulties with maintaining existing collaborations relating to the development and/or commercialization of our product candidates, or establishing new ones on a timely basis or on acceptable terms, or at all;*
- *The terms and conditions of any future strategic collaborations relating to our product candidates;*
- *The degree of market acceptance that XACIATO and any future product achieves;*
- *Coverage and reimbursement levels for XACIATO and any future product by government health care programs, private health insurance companies and other third-party payors;*
- *Our loss of, or inability to attract, key personnel;*
- *A change in the FDA's prior determination that the Center for Devices and Radiological Health would lead the review of a premarket approval application for potential marketing approval of Ovaprene;*

- *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;*
- *Unfavorable differences between preliminary, interim or topline clinical study data reported by us and final study results;*
- *Communication from the FDA or another regulatory authority, including a complete response letter, that such agency does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that such agency interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *Failure to select product candidates that capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas within women's health including due to our limited financial resources;*
- *Loss or impairment of our in-licensed rights to develop and commercialize XACIATO and our product candidates;*
- *Our payment and other obligations under our in-license and acquisition agreements for XACIATO and our product candidates;*
- *Developments by our competitors that make XACIATO, or any potential product we develop, less competitive or obsolete;*
- *Unfavorable or unanticipated macroeconomic factors, geopolitical events or conflicts, public health emergencies, or natural disasters;*
- *Weak interest in women's health relative to other healthcare sectors from the investment community or from pharmaceutical companies and other potential development and commercialization collaborators;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems and data, our financial resources and other assets, or the technology systems and data of third parties on which we rely;*
- *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 XACIATO and certain of our product candidates that expose them to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Dependence on grant funding to advance the development of several of our product candidates;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results or results that differ from investors' expectations for such results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could cause investors to experience losses and subject us to securities class-action litigation;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *Development of safety, efficacy or quality concerns related to our product or product candidates (or third-party products or product candidates that share similar characteristics or drug substances), whether or not scientifically justified, leading to delays in or discontinuation of product development, product recalls or withdrawals, diminished sales, and/or other significant negative consequences;*
- *Product liability claims or governmental investigations;*
- *Changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, pricing and/or marketing of our products, product candidates and related intellectual property, health care information and data privacy and security laws, transparency laws and fraud and abuse laws, and the enforcement thereof affecting our business; 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.

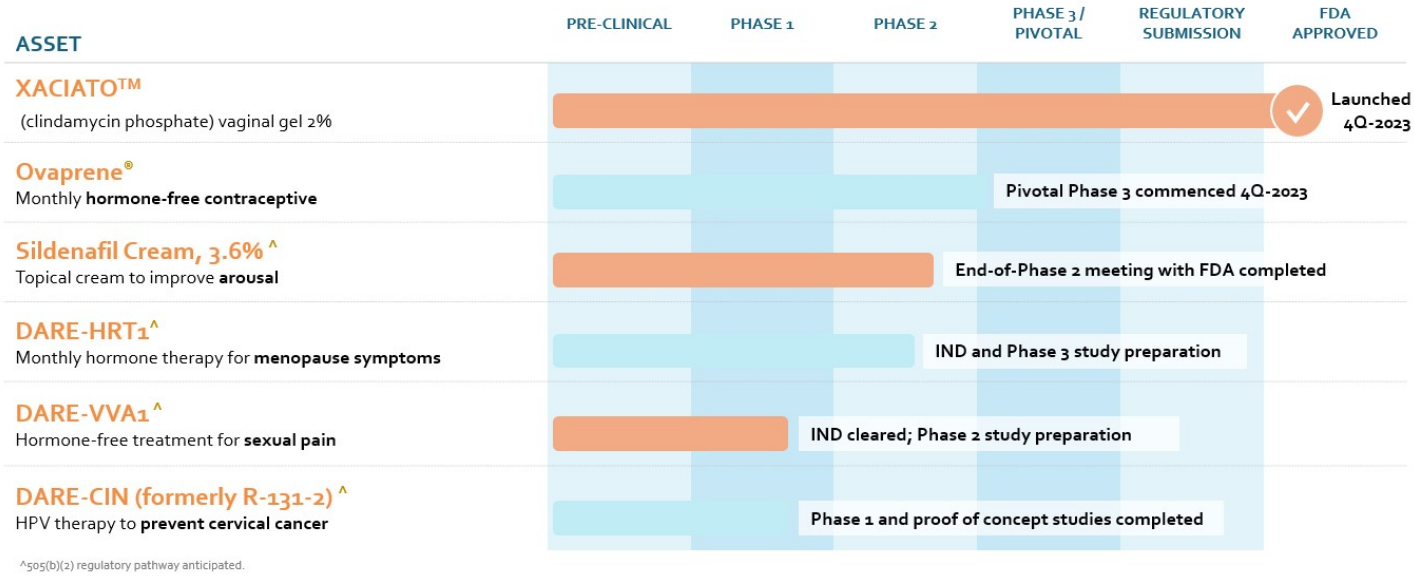
### Overview

We are a biopharmaceutical company committed to advancing innovative products for women's health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility. 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, to take those candidates through mid to late-stage clinical development or regulatory approval, and to establish and leverage strategic collaborations to achieve commercialization. We and our wholly-owned subsidiaries operate in one business segment.

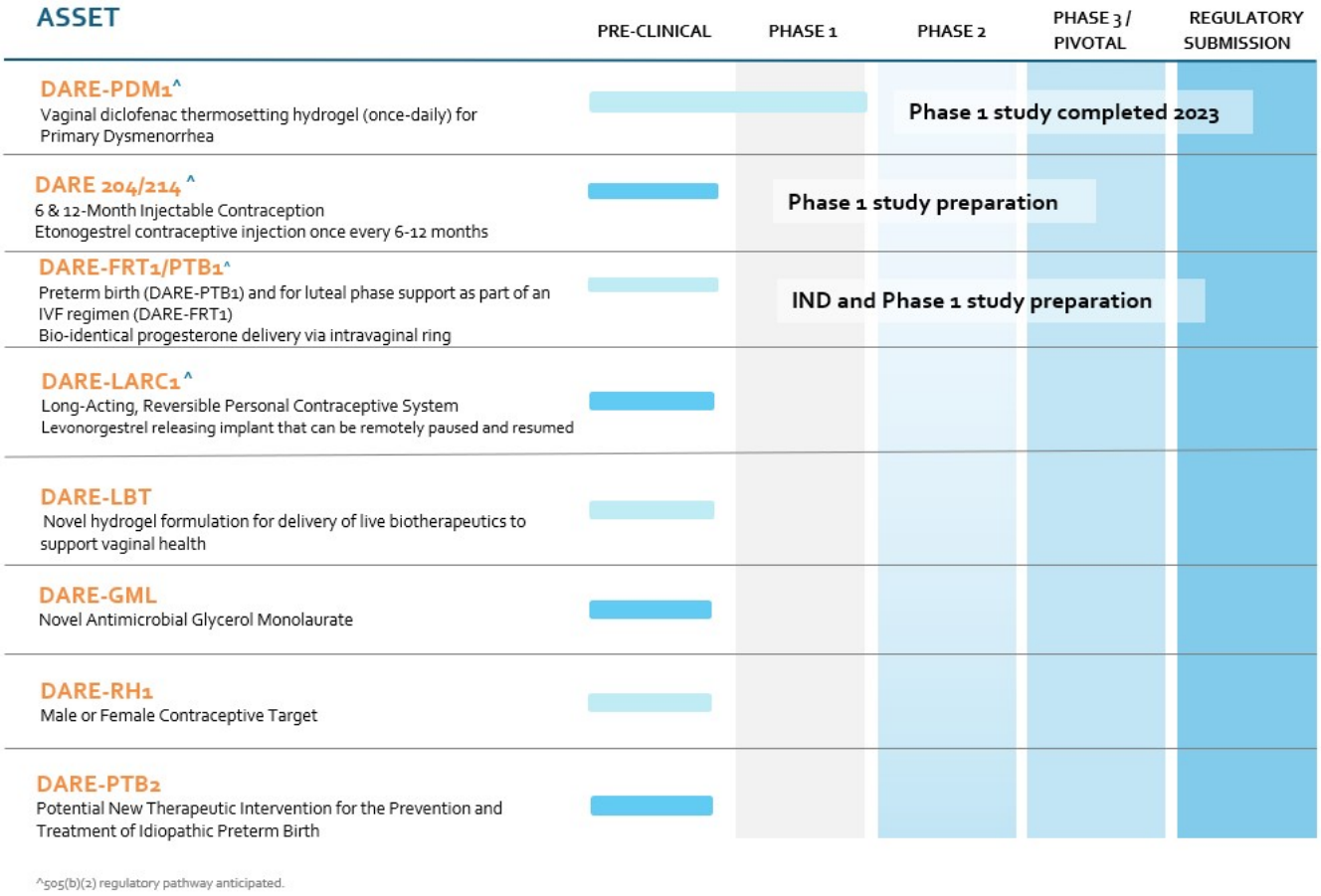
The first FDA-approved product to emerge from our portfolio of women's health product candidates is XACIATO (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe). XACIATO was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In March 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. Accordingly, our potential future revenue from the commercialization of XACIATO will consist of royalties based on net sales and milestone payments from Organon. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023.

We began assembling our diverse portfolio of clinical-stage product candidates and pre-clinical programs in 2017 through acquisitions, exclusive in-licenses and other collaborations. Our programs target unmet needs in women's health in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility, and aim to expand treatment options, enhance outcomes and improve ease of use for women. We are primarily focused on progressing the development of our existing portfolio of product candidates. However, we also explore opportunities to expand our portfolio by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on women's health. We believe the product candidates in our portfolio offer innovative approaches that may provide meaningful benefits over current therapeutic or contraceptive options. We evaluate potential new product candidates based on similar selection criteria as we applied in assembling our existing portfolio. Our product candidates, if approved for commercial sale, would be physician prescribed products.

The following graphic summarizes the product and product candidates in our portfolio in advanced clinical development (Phase 2-ready to Phase 3), including targeted indications, development status and milestones:



The following graphic summarizes the product candidates in our portfolio in earlier stages of development, including targeted indications, development status and milestones:



**Our Strategy**

Our goal is to bring to market innovative products that address persistent unmet needs in women's health, primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility - areas in women's health that we believe represent compelling and meaningful market opportunities for products that enhance outcomes and convenience. We plan to achieve this goal by advancing the product candidates in our portfolio through mid- to late-stage clinical development, and potentially regulatory approval, as well as by establishing and leveraging strategic partnerships and other collaborations to complete product development and commercialize our products, if approved. We are primarily focused on progressing the development of our existing portfolio of product candidates. However, we also explore opportunities to expand our portfolio through both business development activities that may result in acquiring, or acquiring access to, new product candidates through in-licensing or other collaborative arrangements, and leveraging platform technology assets we previously acquired or in-licensed from third parties that can be modified with different active pharmaceutical ingredients to address multiple indications. As with our current portfolio, we seek innovations in women's health that have (a) attractive market opportunities with the potential to address an unmet medical need, including through new formulations, manners of application or delivery methods of well-known drug substances that result in novel, product candidates customized for women, (b) human proof-of-concept clinical data previously generated by third parties and/or potential to utilize the FDA's 505(b)(2) pathway, and (c) potential to become a first-in-category or first-line product.

Key elements of our business strategy are as follows:

- *Advance clinical development of the product candidates in our portfolio through mid- to late-stage clinical development or regulatory approval* . In 2023, we continued to make important progress in the clinical development of our product candidates, including with the completion of, and positive topline results from the exploratory Phase 2b RESPOND study of Sildenafil Cream, 3.6%, the Phase 1/2 study of DARE-HRT1 and the Phase 1 study of DARE-PDM1, as well as FDA clearance of our investigational new drug, or IND, application for DARE-VVA1 and the commencement of the pivotal Phase 3 study of Ovaprene.
- *Explore opportunities to expand our portfolio, with women's health as our sole focus* . While simultaneously advancing our current portfolio, we intend to continue to identify other important areas of unmet need in women's health and to explore opportunities to build our product pipeline by acquiring or in-licensing new programs or leveraging assets we previously acquired or in-licensed to create new programs that meet our selection criteria. For example, in 2023, we entered into a license agreement under which we acquired exclusive rights to develop and commercialize in the U.S. an investigational anti-viral vaginal insert, which we refer to as DARE-CIN, for the treatment of cervical intraepithelial neoplasia and other human papillomavirus (HPV)-related pathologies.
- *Pursue strategic collaborations to fund our business and/or enhance our development and commercialization capabilities* . We intend to develop and maintain strategic relationships with commercial-stage companies that are leaders or emerging leaders in women's health, as well as with other entities, where we believe such collaborations will help fund our business or accelerate or otherwise improve upon our clinical development and regulatory strengths and/or product manufacturing and commercialization capabilities. Examples of our efforts to date include our license agreement with Organon to commercialize XACIATO, our license agreement with Bayer to commercialize Ovaprene, if approved and the license becomes effective, and our Cooperative Research and Development Agreement, or CRADA, with the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, for the conduct of the Phase 3 clinical study of Ovaprene.
- *Seek non-dilutive sources of funding to support product development.* We intend to advance development of our programs through a variety of means, including through non-dilutive funding. To date, we have received non-dilutive funding to support various aspects of development of seven of our product candidates. We intend to continue to explore grants and other forms of non-dilutive funding to support development of our product candidates.

**XACIATO™**

XACIATO (clindamycin phosphate) vaginal gel, a lincosamide antibacterial, received FDA approval in December 2021 for the treatment of bacterial vaginosis in female patients 12 years of age and older.

XACIATO is our first and, to date, only approved product. We achieved FDA approval of XACIATO three years after acquiring rights to the program. We commenced and completed a successful pivotal clinical study, prepared and filed a new drug application, or NDA, with the FDA and received notification from the FDA of U.S. marketing approval, all during the COVID-19 pandemic.

In March 2022, we entered into an agreement with Organon which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. Accordingly, our potential future revenue from the commercialization of XACIATO will consist of royalties based on net sales and milestone payments from Organon. See "Strategic Agreements for Product Commercialization" below for further discussion of the terms of our agreement with Organon. We remained the NDA holder of XACIATO until December 2023, at which time the NDA was transferred by the FDA to Organon, and Organon assumed all manufacturing responsibilities, regulatory and compliance matters. Organon is also responsible for commercializing, promoting, determining pricing, and negotiating reimbursement matters related to XACIATO. See "Sales and Marketing" below for further discussion of manufacturing for XACIATO and "Government Regulation—U.S. Government Regulation" below for discussion of applicable laws and compliance requirements. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023.

In December 2023, we entered into a royalty interest financing agreement pursuant to which we sold an interest in the royalty and milestone payments we receive from Organon in respect of the net sales of XACIATO by Organon. See "Royalty Interest Financing Agreement" below for a discussion of this agreement.

XACIATO previously received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis in women. As a result of the QIDP designation, XACIATO was eligible to receive a five-year extension of the three years of data exclusivity in the U.S. available to the product based on the submission of new clinical data that were essential to its approval. The FDA granted XACIATO for the treatment of bacterial vaginosis in female patients 12 years of age and older three years of data exclusivity, which was extended by five years, such that the data exclusivity period will expire on December 7, 2029. XACIATO has also been designated as a reference listed drug by the FDA for purposes of future generic drug development. The data exclusivity period should block the FDA from approving either a subsequent abbreviated NDA or 505(b)(2) NDA that relies in whole or in part on our protected clinical data. See also "Government Regulation - U.S. Government Regulation- New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension" below. Additionally, see the discussion of patents and patent applications related to XACIATO under "Intellectual Property—Patents" below.

**Our Pipeline: Clinical-Stage Programs**

***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, investigational hormone-free monthly intravaginal contraceptive designed to be worn conveniently over multiple weeks (one menstrual cycle) and with the potential to achieve “typical use” contraceptive efficacy approaching that of current FDA-approved non-implanted hormonal contraceptive methods (pills, patches and vaginal rings), which is approximately 91% typical use efficacy. Typical use contraceptive efficacy refers to the expected rate of pregnancy prevention during the first year of actual use of a method, including sometimes using the method in a way that is not correct or not consistent. Ovaprene features a proprietary knitted polymer barrier to physically block sperm from entering the cervical canal within a silicone-reinforced ring that releases non-hormonal agent ferrous gluconate to impede sperm motility. Unlike current FDA-approved monthly intravaginal contraceptives, Ovaprene does not contain hormones, but, consistent with those monthly intravaginal contraceptives, 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 composed of both device and drug components and is considered a combination product by the FDA. There is no predicate device for Ovaprene (i.e., there is no existing FDA-approved product that the FDA can use to compare with Ovaprene). As such, Ovaprene will be reviewed via a premarket approval, or PMA, process and not a 510(k) premarket submission. While the regulatory process for such a novel product can require more interactions and research to support FDA approval, the benefit is a clearly differentiated product. Ovaprene previously underwent a request for designation process with the FDA that determined that the Center for Devices and Radiological Health, or CDRH, would lead the review of a PMA application for potential marketing approval in the U.S.

***Clinical Data***

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 (ClinicalTrials.gov ID: NCT03598088). 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 PMS, and less than five PMS per HPF is considered indicative of contraceptive effectiveness.

***Pivotal Phase 3 Clinical Study***

In December 2023, we announced commencement of the multi-center, single arm, non-comparative, pivotal Phase 3 clinical study of Ovaprene to evaluate its effectiveness as a contraceptive along with its safety and acceptability (ClinicalTrials.gov ID: NCT06127199). The study aims to enroll sufficient participants across approximately 20 study sites in the U.S. to have approximately 250 participants complete approximately 12 months (13 menstrual cycles) of use. Based on typical dropout rates for contraceptive efficacy studies, we will seek to enroll more than double the number of subjects we target to complete 13 menstrual cycles of use. Before commencing the study, we worked with our collaborators at the National Institutes of Health, or NIH, and at Bayer to review and implement study design considerations provided by the FDA with its Investigational Device Exemption, or IDE, approval letter, which we believe will further position the Phase 3 study to collect safety and effectiveness data to enable the preparation of, and to support the submission of, a PMA application for Ovaprene. The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. If successful, we expect the study to support a PMA application to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

The Phase 3 study is being conducted under our Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, part of the NIH, and within NICHD's Contraceptive Clinical Trial Network. We and NICHD will each provide medical oversight and final data review and analysis for the study and will work together to prepare the final report of the results of the study. We are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million to NICHD to be applied toward the costs of conducting the Phase 3 study, $5.0 million of which has been paid. NICHD is responsible for the other costs related to the conduct of the Phase 3 study and for managing the payment of expenses to the contract research organization for the study, the clinical sites, and other parties involved with the study. We expect to make the remaining $0.5 million payment to NICHD in the third quarter of 2024. In the future, depending on the duration of the enrollment period and number of subjects enrolled in the Phase 3 study, there may be costs associated with the study that are not reflected in the current budget under the CRADA, in which case, we and NICHD would discuss the mechanism to potentially provide for additional future payments by us in support of the Phase 3 study. We do not expect any such potential additional amounts to be payable in 2024.

In addition to the CRADA, we are collaborating with ADVA-Tec, Inc., or ADVA-Tec, and Bayer HealthCare LLC, or Bayer, for the development and commercialization of Ovaprene as part of two strategic collaborations announced in March 2017 and January 2020, respectively. See "Strategic Agreements for Pipeline Development" and "Strategic Agreements for Product Commercialization" 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%, or Sildenafil Cream, an investigational proprietary cream formulation of sildenafil, a phosphodiesterase-5 inhibitor and the active ingredient in the male erectile dysfunction drug Viagra®, for topical administration to the female genitalia for treatment of FSAD. Today, there are no treatments approved by the FDA for FSAD and thus, there are no efficacy endpoints that have been previously validated in a Phase 3 pivotal study for potential treatments for FSAD. Our Phase 2b RESPOND clinical study of Sildenafil Cream, which is discussed further below, was a first of its kind Phase 2b clinical study that included patient reported outcome (PRO) instruments to screen eligible women and a number of primary, secondary, and exploratory PRO assessments to measure improvement in localized genital sensations of arousal and reduction in the distress that women experience with FSAD. We are developing the study design for Phase 3 clinical studies of Sildenafil Cream with ongoing feedback from the FDA coming out of our end-of-Phase 2 meeting with the FDA held in late 2023. We expect the FDA to complete its review of the Phase 2b RESPOND clinical study data and provide comments within the second quarter of 2024 on the proposed primary and secondary PRO endpoints for the planned Phase 3 pivotal trials of Sildenafil Cream to support potential product registration and labeling. 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 in the U.S. for the treatment of women suffering from FSAD. If approved, Sildenafil Cream could be the first FDA-approved FSAD treatment option for women.

FSAD, as described in the Diagnostic and Statistical Manual of Mental Disorders 4th Edition Text Revision ("DSM IV TR"), 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 (also described in DSM IV TR), which is characterized primarily by lack or absence of sexual fantasies and desire for sexual activity (also commonly referred to as low libido). As with erectile dysfunction in men, FSAD in women is associated with insufficient blood flow to the genitalia. Sildenafil Cream is designed to facilitate vasodilation and increase genital blood flow, and, as a result, to provide improvements in the female genital arousal response, while avoiding systemic side effects observed with oral formulations of sildenafil.

***Clinical Data***

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 postmenopausal women using a crossover study design, topical sildenafil cream demonstrated significantly lower systemic exposure to sildenafil compared to a 50 mg oral sildenafil dose, and topical sildenafil cream 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. Of the 35 women enrolled, 31 (15 premenopausal and 16 postmenopausal) completed the study. The primary objective was to evaluate the efficacy of Sildenafil Cream compared to placebo cream assessed by participant-reported levels of subjective cognitive sexual arousal and by physiological genital arousal response. Sildenafil Cream 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.

A Phase 1, single-dose, double-blind, placebo-controlled, two-way crossover study to evaluate the feasibility of using thermography to assess the pharmacodynamics (PD) of Sildenafil Cream 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 demonstrated significantly greater increases in genital temperature compared to placebo cream, indicating a positive impact on genital blood flow during the 30-minute post-dosing testing session, with statistical separation from placebo cream within the first 15 minutes after dosing. Additionally, significantly greater self-reported arousal responses were reported during Sildenafil Cream visits compared to placebo cream visits.

In 2019, as part of our exploratory Phase 2b clinical program for Sildenafil Cream, we completed a non-interventional study, or the content validity study, designed to identify and document the genital arousal symptoms that are most important and relevant to women with FSAD. 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. The findings of that study helped facilitate alignment with the FDA on acceptable efficacy endpoints in our exploratory Phase 2b clinical study and future Phase 3 program, including with respect to the patient reported outcome, or PRO, instruments to be used to screen eligible patients with FSAD and to measure achievement of the primary efficacy endpoint in the Phase 2b study.

In April 2023, we initiated subject enrollment in a Phase 1, single-dose, double-blind, placebo-controlled, 3-way crossover clinical study of Sildenafil Cream using thermography to assess the PD and pharmacokinetic (PK) characterization of Sildenafil Cream. The study was closed in March 2024. Sildenafil Cream was safe and well tolerated in the study. Data from the study will expand our existing clinical and nonclinical data for Sildenafil Cream and are expected to support the ongoing development of Sildenafil Cream as a potential treatment for FSAD.

In June 2023, we announced topline results from our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream in premenopausal women with FSAD, and in July and November 2023, we announced additional findings based on further analyses of data from the study. In February 2024, we presented additional findings from the study at the Annual Meeting of the International Society for the Study of Women's Sexual Health. During the multi-center, double-blind, randomized, placebo-controlled study, subjects used Sildenafil Cream and placebo cream in their home setting over 12 weeks following a 4-week non-drug run-in period and a 4-week, single-blind placebo run-in period. A total of 252 subjects were enrolled in the 4-week single-blind placebo run-in period and a total of 200 subjects were randomized to the 12-week double-blind dosing period. A total of seven subjects were randomized but not treated in the double-blind dosing period. In the intent to treat (ITT) population, 99 subjects were randomized to the Sildenafil Cream group and 94 subjects were randomized to the placebo cream group. The study did not meet its co-primary or secondary endpoints, which were measured based on the ITT population. However, subjects in the Sildenafil Cream group showed improvements in multiple pre-specified exploratory endpoints that evaluated various aspects of the sexual experience, and we view the study results as positive and enabling of advancement of Sildenafil Cream into Phase 3 clinical development, which was confirmed by successful completion of our end-of-Phase 2 meeting with the FDA. The RESPOND study was a first of its kind Phase 2b clinical study that enabled us to identify a subgroup of patients who are most likely to benefit from Sildenafil Cream therapy and achieve meaningful improvement in their FSAD symptoms. Based on post hoc analyses, in a subgroup of study subjects consisting of healthy premenopausal women with FSAD, including those who suffered from a lack of sexual desire due to their decreased arousal, Sildenafil Cream demonstrated improved arousal sensation, desire, orgasm, as well as reduced stress, guilt, and embarrassment about the sexual dysfunction.

***End-of-Phase 2 Meeting and Phase 3 Program***

In January 2024, we announced the successful completion of an end-of-Phase 2 meeting with the FDA. We and the FDA aligned on key elements of the Phase 3 program to support an NDA filing, including confirming that FSAD is acceptable as an indication, the clinical trials can be conducted in a premenopausal FSAD-only population,

and 12-weeks of blinded treatment to assess efficacy may be acceptable, provided that the trials are adequately powered for efficacy assessment. This is a shorter period of blinded treatment than the 24 weeks recommended in the FDA's 2016 draft guidance for industry on developing drugs for the treatment of low sexual interest, desire and/or arousal in women. Within the second quarter of 2024, we expect additional feedback from the FDA on our proposed primary and secondary patient reported outcome endpoints for the Phase 3 pivotal trials of Sildenafil Cream, as well as additional information on data that may be needed in an NDA submission to appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration. We have also requested clarification on the safety database (size and duration exposure) that the FDA will require for an NDA submission.

We believe FSAD is an area of significant unmet need and that the improvements demonstrated in the Phase 2b RESPOND study in the patient population we plan to study in the Phase 3 program provided an important step towards advancing development of Sildenafil Cream for this challenging condition. We continue to work toward finalizing the plan for Phase 3 clinical development of Sildenafil Cream.

We are developing Sildenafil Cream with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC (which we refer to collectively as SST) under our license and collaboration agreement announced in February 2018. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of this collaboration.

***DARE-HRT1***

DARE-HRT1 is a unique intravaginal ring, or IVR, designed to deliver bio-identical 17β-estradiol and bio-identical progesterone continuously over a 28-day period as part of a menopausal hormone 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 therapy is considered the most effective treatment for vasomotor symptoms, or VMS, commonly referred to as hot flashes, and the genitourinary syndrome of menopause, and it has been shown to prevent bone loss and fracture.

Following clinical development, we intend to leverage the large body of existing safety and efficacy data on estradiol and progesterone, the active ingredients in DARE-HRT1, to utilize the FDA's 505(b)(2) pathway to obtain marketing approval in the U.S. of DARE-HRT1 for the treatment of moderate-to-severe VMS due to menopause in women with intact uteri. Based on pre-IND communications with the FDA and the topline PK data from our Phase 1/2 clinical trial of DARE-HRT1, which is discussed below, we believe FDA approval of DARE-HRT1 for that indication is achievable via the FDA's 505(b)(2) pathway supported by a single, placebo-controlled Phase 3 clinical trial of DARE-HRT1, with safety evaluations out to 12 months, and a scientifically justified PK "bridge" (via a relative bioavailability trial) between DARE-HRT1 and the selected listed estradiol and progesterone drugs. We are conducting activities necessary to enable submission of an IND application to the FDA for a pivotal Phase 3 clinical study of DARE-HRT1. We do not plan to conduct the Phase 3 study until after we secure additional capital.

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, and non-oral concurrent dosing of bio-identical progesterone in combination with bio-identical estradiol.

***Clinical Data***

In January 2023, data from our Phase 1 clinical trial of DARE-HRT1 were published in *Menopause: The Journal of The North American Menopause Society,* or the *Menopause* journal, in an article entitled, "Evaluation of 28-day estradiol and progesterone vaginal rings in a phase 1 clinical pharmacokinetic study." We previously announced positive topline results from the study in June 2021. The randomized, open-label, three-arm, parallel group trial evaluated the PK and safety of DARE-HRT1 in approximately 30 healthy, postmenopausal women with intact uteri, and was conducted by our wholly-owned Australian subsidiary at two specialty women's health sites in Australia. Women in the first arm received one IVR designed to release 17β-estradiol (E2) at a rate of 80 µg/d and progesterone (P4) at 4 mg/d, or the 80/4 IVR. Women in the second arm received one IVR designed to release E2 at a rate of 160 µg/d and P4 at 8 mg/d, or the 160/8 IVR. Women in the third arm received oral Estrofem® (1 mg E2) and oral Prometrium® (100 mg P4) both daily for 29 days. The primary objective of the study was to describe the PK parameters of the 80/4 IVR and the 160/8 IVR. Secondary endpoints of the study were to assess the safety and tolerability of the IVRs and compare the systemic exposure of E2, estrone, and P4 in the IVR groups with the oral group. Blood samples were taken predose then intensively over the first day (Day 1) and periodically thereafter over the remaining 27 days. After removal of the IVRs on the morning of Day 29, intensive samples were collected. Similar procedures were conducted with women enrolled in the oral group.

The journal article concluded that the 80/4 IVR and the 160/8 IVR gave similar steady-state concentrations of E2 as seen with drug products approved by the FDA for treatment of VMS and genitourinary symptoms of menopause, and that the E2 concentrations of the study support the potential of DARE-HRT1 as a new option for hormone therapy for treatment of VMS and vaginal symptoms associated with menopause. The IVRs were well tolerated, and no serious adverse events were reported.

DARE-HRT1 has also been evaluated in a Phase 1/2 clinical trial conducted by our wholly owned subsidiary in Australia. The randomized, open-label, two-arm, parallel group Phase 1/2 study of DARE-HRT1 was designed to evaluate the PK of the same two versions of DARE-HRT1 as were evaluated in our earlier Phase 1 clinical study, the 80/4 IVR and the 160/8 IVR, in approximately 20 healthy, postmenopausal women with intact uteri. In the study, women were randomized (1:1) to either the 80/4 IVR or the 160/8 IVR and used DARE-HRT1 for three 28-day cycles, inserting a new IVR monthly. The study also collected safety, usability, acceptability and symptom-relief data, including VMS as well as the vaginal symptoms of menopause. Preliminary genitourinary syndrome of menopause (GSM) treatment efficacy was estimated by measuring changes from baseline in vaginal pH, vaginal maturation index (VMI), and changes in the severity of GSM symptoms. Preliminary systemic VMS efficacy was measured by changes in responses to the Menopause-Specific Quality of Life (MENQOL) questionnaire. Acceptability was assessed by product experience surveys.

In 2023, data from the Phase 1/2 study of DARE-HRT1 were published in the *Menopause* journal in articles entitled, "A phase 1/2, open-label, parallel group study to evaluate the safety and pharmacokinetics of DARE-HRT1 (80 µg estradiol/4 mg progesterone and 160 µg estradiol/8 mg progesterone intravaginal rings) over 12 weeks in healthy postmenopausal women" (*Menopause* 30(8):p 817-823, August 2023) and "A phase 1/2, open-label, parallel group study to evaluate the preliminary efficacy and usability of DARE-HRT1 (80 µg estradiol/4 mg progesterone and 160 µg estradiol/8 mg progesterone intravaginal rings) over 12 weeks in healthy postmenopausal women" (*Menopause* 30(9):p 940-946, September 2023).The first article ( *Menopause* 30(8):p 817-823, August 2023) found that both versions of DARE-HRT1 evaluated in the Phase 1/2 study were safe and released E2 in systemic concentrations, which were in the low, normal premenopausal range and that systemic P4 concentrations predict endometrial protection. All treatment emergent adverse events were mild or moderate and were distributed similarly among the 80/4 IVR and the 160/8 IVR users. The second article (*Menopause* 30(9):p 940-946, September 2023) found that (a) preliminary local GSM treatment efficacy was supported by significant decreases in vaginal pH and percentage (%) parabasal cells, and significant increases in the overall VMI and % superficial cells for both DARE-HRT1 groups (all P values <0.01) and (b) preliminary VMS efficacy was supported by significant decreases in all domains of the MENQOL questionnaire from baseline for both dosing groups (all P values <0.01). Both articles concluded that data from the Phase 1/2 study support further development of DARE-HRT1 for the treatment of menopausal symptoms.

We are developing DARE-HRT1 under our license agreement with Catalent JNP, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

***DARE-VVA1***

DARE-VVA1 is a proprietary investigational formulation of tamoxifen for intravaginal administration. We are developing DARE-VVA1 as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of vulvar and vaginal atrophy, or VVA, associated with menopause. Tamoxifen is a well-known and well-characterized selective estrogen receptor modulator, or SERM. Tamoxifen has unique properties that produce different effects (estrogen agonist or estrogen antagonist) 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 elicit an estrogen-like response. This has the potential to have a favorable effect on vaginal cytology. VVA is an inflammation and thinning of the vaginal epithelium due to chronic hypo-estrogenism, which is the reduction in levels of circulating estrogen. Typical symptoms include vaginal dryness, itching and burning, and dyspareunia. VVA is a common condition in postmenopausal women and women with, or with a history of, HR+ breast cancer who received anti-cancer therapy. The prevalence of VVA in postmenopausal women is over 50% and survey data indicate only 56% of women experiencing menopausal vaginal changes discuss these symptoms with healthcare professionals, indicating that the syndrome is often underdiagnosed. Commonly used therapies for VVA are estrogen-based and are 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 or occurrence of disease. We believe there is a clear unmet medical need for an effective non-hormonal treatment for VVA.

In December 2023, we announced FDA clearance of our IND application for DARE-VVA1, which was supported by results from our Phase 1/2 clinical study of DARE-VVA1 (discussed below), and we are planning for a Phase 2 randomized, double-blinded, placebo-controlled, dose-finding clinical study of DARE-VVA1. We do not plan to conduct the Phase 2 study until after we secure additional capital. At the conclusion of our development program, if successful, 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.

***Clinical Data***

An exploratory study of vaginal administration of tamoxifen in four healthy postmenopausal women diagnosed with VVA published in *Clinical and Experimental Obstetrics & Gynecology* demonstrated that tamoxifen self-administered intravaginally for three months clinically benefited women with symptoms of VVA without significant systemic absorption of the study drug. In the open-label prospective cohort study with no placebo arm, participants were instructed to self-administer a vaginal suppository containing tamoxifen (20 mg) daily for one week and twice weekly for three months. The study treatment was effective in reducing vaginal pH and vaginal dryness. When measured after eight weeks on the study treatment, serum tamoxifen levels were negligible, 5.8 ng/ml (median), with a range of 1.0 to 10.0 ng/ml. In comparison, after three months of once daily administration of oral dose of 20-mg tamoxifen, Nolvadex® (tamoxifen citrate) tablets, the average steady state plasma concentration of tamoxifen is 122 ng/ml (range of 71 to 183 ng/ml).

DARE-VVA1 has also been evaluated in a Phase 1/2 clinical study conducted by our wholly-owned subsidiary in Australia. In November 2022, we announced topline results from of our Phase 1/2 clinical study of DARE-VVA1 conducted by our wholly-owned subsidiary in Australia. The randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study enrolled 17 postmenopausal women with moderate-to-severe VVA and evaluated the safety, tolerability, plasma PK and pharmacodynamics (PD) of DARE-VVA1. The age of the 17 study participants ranged from 49 to 68 years, with an average age of 60.9 years. Participants were randomly allocated to one of five treatment groups (approximately four participants per group) that evaluated four dose levels of DARE-VVA1 (1 mg, 5 mg, 10 mg, and 20 mg tamoxifen) and a placebo. Following a screening visit, DARE-VVA1 was self-administered by study participants intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants had serial blood sampling for PK analysis and underwent safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants attended a safety follow-up visit. Fourteen participants completed the study. The primary endpoints of the study evaluated the safety and tolerability of DARE-VVA1 by vaginal administration and determined the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints evaluated preliminary efficacy and PD of DARE-VVA1 in terms of the most bothersome vaginal symptom and changes in vaginal cytology and pH.

In 2023, data from our Phase 1/2 study of DARE-VVA1 were published in Climacteric, the official journal of the International Menopause Society, in an article entitled, “Pharmacokinetics, safety and preliminary pharmacodynamic evaluation of DARE-VVA1: a soft gelatin capsule containing tamoxifen for the treatment of

vulvovaginal atrophy." The article concluded that DARE-VVA1 was safe and resulted in minimal systemic exposure to tamoxifen. Adverse events were mild to moderate in severity and distributed similarly among the DARE-VVA1 and placebo groups. Plasma tamoxifen concentrations were highest among women using DARE-VVA1 20 mg, but the maximum mean (standard deviation) plasma tamoxifen concentrations on day 1 and day 56 of the treatment period were less than 14% of those measured after one oral tamoxifen dose. The article also concluded that preliminary efficacy data support further development of DARE-VVA1. The article found that DARE-VVA1 users had significant decreases from pre-treatment baseline in vaginal pH and proportion of vaginal parabasal cells ($p = 0.04$ for both endpoints). Women randomized to use DARE-VVA1 10 mg or DARE-VVA1 20 mg experienced the largest treatment impact. The severity of vaginal dryness and dyspareunia decreased significantly from baseline with DARE-VVA1 use ($p = 0.02$ for both endpoints).

We acquired the DARE-VVA1 program through our acquisition of Pear Tree Pharmaceuticals in 2018. See "Strategic Agreements for Pipeline Development" below for discussion of that merger agreement.

***DARE-CIN***

DARE-CIN (formerly referred to as R-131-2) is an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert, which we plan to develop for the treatment of cervical intraepithelial neoplasia, or CIN (also known as cervical dysplasia), and other HPV-related pathologies. CIN is a precancerous condition in women strongly linked to HPV infection, the most common sexually transmitted infection in the U.S. Disease severity is classified on a scale from one to three based on how much epithelial tissue in the cervix has abnormal cells. There is no FDA-approved non-surgical pharmaceutical intervention to treat CIN2 or CIN3 (collectively referred to as CIN2+). Current surgical procedures to treat cervical dysplasia are invasive and can adversely impact future pregnancies. We believe a non-surgical pharmaceutical approach could provide women with an important alternative to surgical procedures to treat cervical dysplasia.

We are conducting limited activities to support an IND submission to the FDA to enable Phase 2 clinical development of DARE-CIN in the United States. We do not plan to conduct the Phase 2 study until after we secure additional capital.

***Clinical Data***

DARE-CIN was previously evaluated in a proof-of-concept clinical study and the results demonstrated its potential as a self-applied therapy for HPV infection and related cervical lesions. DARE-CIN was also previously evaluated in a Phase 1 clinical study to assess PK.

We are developing DARE-CIN under our license agreement with Douglas Pharmaceuticals, Limited. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

***DARE-PDM1***

DARE-PDM1 is an investigational proprietary hydrogel formulation of diclofenac for vaginal administration designed to treat primary dysmenorrhea. DARE-PDM1 utilizes our proprietary hydrogel technology to vaginally deliver the active pharmaceutical ingredient, diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), in a novel way for the treatment of primary dysmenorrhea. Primary dysmenorrhea is defined as painful menstruation in girls and women with normal pelvic anatomy, typically described as cramping pain in the low back or lower abdomen before or during the menstrual period. Oral NSAIDs, such as diclofenac, are often recommended for temporary relief from the painful symptoms of primary dysmenorrhea. Because there are currently no FDA-approved vaginal diclofenac treatment options for primary dysmenorrhea, DARE-PDM1 has the potential to be a first-in-category product, delivering diclofenac in a convenient vaginal format that may extend the duration of pain relief and reduce the risks associated with the oral delivery of NSAIDs. According to the American College of Obstetricians and Gynecologists' Committee on Adolescent Health Care, dysmenorrhea is the most common menstrual symptom among adolescent girls and young women, and most adolescents experiencing dysmenorrhea have primary dysmenorrhea. Prevalence rates of dysmenorrhea vary but range from 50% to 90%.

***Clinical Data***

DARE-PDM1 has been evaluated in a Phase 1 clinical study, DARE-PDM1-001, conducted by our wholly-owned subsidiary in Australia. DARE-PDM1-001 was a multi-center, randomized, placebo-controlled, double-blind, three-arm parallel group study that enrolled approximately 42 healthy, premenopausal women with symptomatic primary dysmenorrhea. This study was designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac PK and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo (vaginal hydrogel, no active ingredient). The study also assessed, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period encompassed approximately three menstrual cycles.

In December 2023, we announced topline data from the DARE-PDM1-001 study. The topline data indicate that the study treatment was well-tolerated, and treatment emergent adverse events profiles were comparable between the DARE-PDM1 treatment groups and the placebo group. All adverse events were mild or moderate; most adverse events (85%) were mild. There were no early discontinuations due to an adverse event, and no serious adverse events were reported.

The vaginal fluid PK results exhibited dose proportionality for the 1% and 3% diclofenac strengths of the DARE-PDM1 study treatment. Additionally, the vaginal fluid PK results demonstrated that for approximately 75% (21/28) of the women in the DARE-PDM1 treatment groups the product was retained in the vaginal canal through 24 hours. The plasma PK results similarly exhibited dose proportionality for the 1% and 3% diclofenac strengths of the DARE-PDM1 study treatment. Plasma levels of diclofenac were at peak plasma concentrations within 3-4 hours for both diclofenac strengths of the DARE-PDM1 study treatment, and diclofenac was no longer detectable in the plasma by 48 hours post study treatment for the majority of subjects in the study. The plasma PK results for both DARE-PDM1 treatment groups indicate that vaginal dosing could result in systemic exposure which is approximately 1,000 times less than that seen from oral use of diclofenac.

The exploratory endpoint that evaluated the preliminary efficacy of DARE-PDM1 versus placebo in reducing dysmenorrhea-associated pain showed a promising signal, with a statistically significant decrease in pelvic/vaginal and lower back pain scores in the 1% diclofenac DARE-PDM1 treatment group compared to the placebo group, as well as a decrease in pain scores in the 3% diclofenac DARE-PDM1 treatment group. Additionally, while most participants used at least one non-pharmacologic pain relief method (e.g., heating pad) for dysmenorrhea-associated pain during the no-treatment, baseline, control cycle, the proportion of participants who used at least one non-pharmacologic pain relief method for dysmenorrhea-associated pain decreased significantly in the DARE-PDM1 treatment groups during the dosing period, but not in the placebo group. There was no difference in the exploratory assessment of frequency of use of rescue medications in the treatment phase between the three groups.

We believe the topline results of the Phase 1 study support continued clinical development of DARE-PDM1 as a treatment for primary dysmenorrhea. At the conclusion of the development program, if successful, we intend to leverage the existing safety and efficacy data for diclofenac to utilize the FDA's 505(b)(2) pathway to obtain marketing approval of DARE-PDM1 in the U.S.

We are developing DARE-PDM1 under our agreements with TriLogic Pharma, LLC, MilanaPharm LLC and Hammock Pharmaceuticals, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of those agreements.

***DARE-204 and DARE-214***

DARE-204 and DARE-214 are formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively. These product candidates are being developed as a sub-cutaneous injectable, longer-acting, reversible method of contraception with a more predictable return to fertility. We plan to conduct Phase 1 clinical studies of DARE-204 and DARE-214 in Australia through our wholly-owned subsidiary in Australia. Additional manufacturing activities are necessary to commence the Phase 1 studies and these activities have not commenced. If we exercise our option and enter into an exclusive worldwide license agreement for DARE-204 and/or DARE-214, at the conclusion of these development programs, if successful, we intend to leverage the existing safety and efficacy data for etonogestrel to utilize the FDA's 505(b)(2) pathway to obtain marketing approval in the U.S.

We are developing DARE-204 and DARE-214 under our development and option agreement with Adare Pharmaceuticals USA, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

***DARE-FRT1 and DARE-PTB1***

DARE-FRT1 and DARE-PTB1 are IVRs designed to release bio-identical progesterone continuously for up to 14 days. DARE-FRT1 is being developed for luteal phase support as part of an in vitro fertilization, or IVF, treatment plan. DARE-PTB1 is being developed for the prevention of preterm birth. DARE-FRT1 and DARE-PTB1 use the same IVR technology platform as DARE-HRT1. We are conducting development activities to support IND submissions and Phase 1 clinical studies of these product candidates. We do not plan to conduct the Phase 1 studies until after we secure additional capital. At the conclusion of these development programs, if successful, 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 and DARE-PTB1 in the U.S.

We are developing DARE-FRT1 and DARE-PTB1 under our license agreement with Catalent JNP, Inc. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of that agreement.

**Our Pipeline: Pre-Clinical Stage Programs**

Our pre-clinical stage programs are:

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **DARE-LBT**, a novel hydrogel formulation for delivery of live biotherapeutics to support vaginal health;
- **DARE-GML**, an intravaginally-delivered potential multi-target antimicrobial agent formulated with glycerol monolaurate (GML), which has shown broad antimicrobial activity, killing bacteria and viruses;
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- **DARE-PTB2**, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein.

DARE-LARC1, our potential user-controlled, long-acting reversible contraceptive, is designed to store and precisely deliver hundreds of therapeutic doses of the contraceptive levonorgestrel over a period of years and to be controlled by the user, without further intervention by a healthcare provider. DARE-LARC1’s woman-centered design seeks to offer the benefits of traditional long-acting reversible contraceptives with the added flexibility and convenience for the user to pause and resume release of levonorgestrel, depending on her desire for fertility or contraceptive protection. Under a grant agreement we entered into in June 2021, as amended, we may receive up to approximately $49.0 million, payable over approximately five years, to advance development of the technology through nonclinical proof of principle studies to enable an IND submission. As of the date of this report, we have received payments totaling approximately $28.4 million under the grant agreement. Additional payments are contingent upon the DARE-LARC1 program's achievement of development and reporting milestones specified in the grant agreement.

The DARE-LBT program has been supported by a private foundation grant of approximately $585,000 under a grant agreement that we entered into in November 2022. The grant funds supported activities related to development of a vaginal thermosetting gel formulation for the delivery of live biotherapeutics that can be reconstituted at the point of care. We believe DARE-LBT merits further development as a delivery vehicle with potential to enhance the availability of novel therapeutics for vaginal health in the United States and worldwide, including in countries with varying climatic conditions and/or where extended storage may be required.

**Sales and Marketing**

We do not have established marketing, sales or distribution infrastructure or capabilities. In order to commercialize any of our product candidates if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. Our approach is to develop an appropriate commercialization strategy for each of our product candidates based on the size of the market opportunity, the level of competition and the anticipated complexity of the launch. As we move our product candidates through development toward, and in some cases, through regulatory approval, we evaluate several options for each product candidate's commercialization strategy. These options include building our own sales force and other commercial infrastructure, entering into strategic marketing partnerships with third parties, including commercial sales organizations or other pharmaceutical or biotechnology companies, out-licensing the product to other pharmaceutical or biotechnology companies, and combinations of these strategies. Organon has global commercial rights to XACIATO under our exclusive license agreement, and we have an exclusive license agreement with Bayer to out-license U.S. commercialization of Ovaprene. Each of these collaborators has established marketing, sales and distribution capabilities in women's health. We expect to continue to evaluate each product opportunity and pursue the commercialization strategy that we believe will maximize the return on our assets in and outside of the U.S. for our stockholders. We have engaged third parties to assist in commercial planning and other commercial readiness activities for our product candidates and intend to continue to do so, as needed.

See “Strategic Agreements for Product Commercialization” below for a discussion of the terms of our out-license agreements.

**Manufacturing and Supply**

We do not own or operate, nor do we expect to own or operate, facilities for manufacturing, storage and distribution, or testing of our product candidates. We rely on third parties to supply and manufacture our product candidates and other materials necessary to conduct pre-clinical testing, clinical trials and other activities required for regulatory approval of our product candidates, and expect to continue to do so in the future. In addition, to the extent our commercialization strategy for any future approved product requires that we undertake commercial supply obligations, we intend to rely on contract manufacturers and suppliers for manufacture, storage, distribution and testing of our finished commercial products and their respective components, including the active pharmaceutical ingredients, or API. These arrangements require less upfront capital expenditure and allow us to maintain a smaller and more flexible infrastructure.

Under the terms of our license agreement with Organon, we were responsible for providing product supply of XACIATO on an interim basis until Organon assumed such responsibility. In March 2022, we entered into a long-term supply and manufacturing agreement with the contract manufacturing organization, or CMO, that provided clinical supplies of XACIATO for our pivotal Phase 3 DARE-BVFREE clinical study. Under the terms of our agreement, the CMO was responsible for obtaining supplies, at our expense, of all components necessary for the manufacture of XACIATO, including the API, clindamycin. In December 2023, Organon assumed our obligations under the agreement with the CMO and our product supply agreement with Organon was terminated.

Under our agreement with ADVA-Tec, ADVA-Tec is responsible for providing all clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, and except under limited circumstances, we may not obtain supplies of Ovaprene from any source other than ADVA-Tec or its CMO and licensor, Poly-Med, Inc. Other than our agreement with ADVA-Tec, we have no long-term arrangements for the production or supply of our product candidates or the materials required to produce them.

Under the terms of our license agreement with SST, SST was responsible for providing clinical supplies of Sildenafil Cream for Phase 2 clinical studies in the U.S., and we are responsible for providing supplies of Sildenafil Cream for Phase 3 clinical development and, if approved, for marketing and sale. Currently, we plan to obtain clinical supplies of Sildenafil Cream from the same CMO that manufactured Sildenafil Cream for the Phase 2b RESPOND clinical study.

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, we may experience manufacturing and supply delays and disruptions in the event we need to engage alternative supply sources, as well as in connection with our current CMOs scaling up production to meet our clinical supply requirements for later stage clinical studies. In addition, some key raw materials or components of our clinical-stage product candidates, including Ovaprene and Sildenafil Cream, have only a single source of supply and alternative supply sources may not be readily available. Global supply chain disruptions, including those related to recent and ongoing geopolitical events, may contribute to manufacturing and supply delays. See ITEM 1A. "RISK FACTORS – Risks Related to Product Research & Development and Regulatory Approval – Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products" below.

**Strategic Agreements for Product Commercialization**

***Organon License Agreement***

In March 2022, we entered into an agreement with Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property we control. In July 2022, we received a $10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue. In July 2023, received a $1.0 million payment from Organon in connection with the amendment to the license agreement we entered into which was also recorded as license fee revenue. In connection with the first commercial sale of a licensed product in the United States, we received the $1.8 million milestone payment from Organon in the fourth quarter of 2023.

Under the terms of the license agreement, as amended, we are entitled to receive tiered double-digit royalties based on net sales and potential future milestone payments of up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets. The royalty period for each licensed product will continue on a country-by-country basis from the first commercial sale of the licensed product in the country until the expiration of the later of (i) the date that no valid patent claim would be infringed in the absence of the license granted under the agreement by the sale of the licensed product in the country, (ii) 10 years after the end of the month in which the first commercial sale of the licensed product in the country occurred, and (iii) the expiration of regulatory market exclusivity for the licensed product in that country.

Unless terminated earlier, the agreement will expire on a product-by-product and country-by-country basis upon expiration of the applicable royalty period for each licensed product. In addition to customary termination rights for both parties, Organon may terminate the agreement in its entirety or on a country-by-country basis at any time in Organon's sole discretion on 120 days' advance written notice.

The agreement includes customary representations and warranties, covenants and indemnification obligations of each party. In addition, the terms of the agreement provide Organon exclusive worldwide rights of first negotiation for specified potential future products of ours.

***Bayer License Agreement***

In January 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 non-refundable payment from Bayer and Bayer agreed to 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.

*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.

**Strategic Agreements for Pipeline Development**

The following is a summary of certain rights and obligations under our strategic agreements and describes expenses incurred during 2023 and our future payment or potential future payment obligations thereunder.

**Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement**

In August 2023, we entered into a license agreement with Douglas Pharmaceuticals Limited, or Douglas, under which we acquired the exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of CIN and other HPV-related pathologies, and an agreement with The University of Manchester, pursuant to which The University of Manchester consented to Douglas' sublicense to us of certain rights it previously granted to Douglas and agreed to grant us a direct license to such rights if its license agreement with Douglas is terminated. As a result of these agreements, we commenced our DARE-CIN program. Under our agreement with Douglas, we received an exclusive, royalty-bearing license to research, develop and commercialize the licensed intellectual property in the United States for the treatment or prevention of all indications for women in female reproductive health. We are entitled to sublicense the rights granted to us under the agreement.

*Milestone Payments.* We agreed to make potential future milestone payments to Douglas of (1) up to $5.25 million in the aggregate upon achieving certain development and regulatory milestones, which may be paid in shares of our common stock, in our sole discretion subject to specified limitations, and (2) up to $64.0 million in the aggregate upon achieving certain commercial sales milestones for each product covered by the licenses granted under the agreement.

*Royalty Payments.* Douglas is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on annual net sales of products and processes covered by the licenses granted under the agreement.

*Efforts.* We must use commercially reasonable efforts to develop and introduce to market at least one product or process.

*Term.* Unless earlier terminated, the agreement expires upon the expiration of the last-to-expire royalty term. In addition to customary termination rights for both parties, we may elect to terminate the agreement at any time, with or without cause, upon advance written notice to Douglas, and Douglas may terminate the agreement if we materially fail to fulfill diligence requirements with respect to product development.

***Hennepin License Agreement***

In August 2022, we entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which we acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. As a result of this license agreement, we commenced our DARE-GML program. Under the agreement, we received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. We are entitled to sublicense the rights granted to us under the agreement.

*Milestone Payments.* We agreed to make potential future development and sales milestone payments of (1) up to $6.25 million in the aggregate upon achieving certain development and regulatory milestones, and (2) up to $45.0 million in the aggregate upon achieving certain commercial sales milestones for each product covered by the licenses granted under the agreement, which may be paid, in our sole discretion, in cash or shares of our common stock.

*Royalty Payments.* Hennepin is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement.

*Efforts.* We must use commercially reasonable efforts to develop and introduce to market at least one product.

*Term.* Unless earlier terminated, the agreement expires in its entirety upon the last to expire royalty term. In addition to customary termination rights for both parties, we may elect to terminate the agreement at any time, with or without cause, on a country-by-country basis, and Hennepin may terminate the agreement if we do not undertake any development work with respect to the licensed intellectual property for five consecutive years from the date of the agreement.

***Cooperative Research and Development Agreement with NICHD***

In July 2021, we entered into a CRADA with the U.S. Department of Health and Human Services ("HHS"), as represented by NICHD, part of the NIH, for the conduct of a pivotal Phase 3 clinical study of Ovaprene. See also “Our Pipeline: Clinical Stage Programs – Ovaprene” above. Pursuant to the terms of the CRADA, we are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million to NICHD to be applied toward the costs of conducting the Phase 3 study, $5.0 million of which has been paid and we expect to make the remaining $0.5 million payment in the third quarter of 2024. NICHD will be responsible for the other costs related to the conduct of the Phase 3 study and will manage the payment of expenses to other parties involved with the study. Either we or NICHD may terminate the CRADA for any reason upon 30 days’ prior written notice to the other party. If the CRADA is terminated before completion of the Phase 3 study, NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study. If we terminate the CRADA before the completion of any active study protocol, we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the study. NICHD may retain and use payments we make under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination, and any unused funds will be returned to us. Under the CRADA, each party granted the other party rights to use their respective background inventions solely to the extent necessary to conduct the activities described in the research plan in the CRADA. Subject to the U.S. government’s nonexclusive, nontransferable, irrevocable, paid-up right to practice any CRADA invention for research or other government purposes, each party will own inventions, data and materials produced by its employees, and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed. The CRADA also contains customary representations, warranties, and indemnification and confidentiality obligations. The CRADA expires five years from its effective date.

***MBI Acquisition***

In November 2019, we acquired Dare MB Inc. (formerly, Microchips Biotech, Inc.), or MBI, to secure the rights to develop a long-acting reversible contraception method that a woman can turn on or off herself, according to her own needs. This candidate is now known as DARE-LARC1.

In connection with the MBI acquisition, we issued an aggregate of approximately 3.0 million shares of our common stock to the holders of shares of MBI’s capital stock outstanding immediately prior to the effective time of the merger and agreed to pay the former MBI stockholders: (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 we acquired in the merger; (c) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products sold by us (but not by sublicensees), subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. We agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to DARE-LARC1. In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events, $1.0 million of which was recorded as contingent consideration on our consolidated balance sheets upon the completion of the MBI acquisition and $250,000 of which

was expensed in 2021. In July 2021, our board of directors elected to make these milestone payments in shares of our common stock, to the extent permissible under the terms of the merger agreement with MBI, and, in September 2021, we issued approximately 700,000 shares of our common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders' representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

***TriLogic and MilanaPharm License Agreement / Hammock Assignment 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 XACIATO, this proprietary technology is formulated with clindamycin for the treatment of bacterial vaginosis. In December 2019, we entered into amendments to each of the Assignment Agreement and License Amendment. In September 2021, we entered into a second amendment to the License Agreement. In March 2022, in connection with entering into our exclusive license agreement with Organon, we entered into a consent, waiver and stand-by license agreement with TriLogic, MilanaPharm and Organon, which further amended the License Agreement.

License Amendment, as amended:

*Milestone Payments.* We paid MilanaPharm $500,000 in connection with the first commercial sale in the United States of XACIATO in the fourth quarter of 2023. We may pay up to $250,000 upon the first commercial sale in the United States of successive licensed products for each vaginal or urological use. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products, we must pay $1.0 million to MilanaPharm.

*Foreign Sublicense Income*. MilanaPharm is eligible to receive 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, MilanaPharm is eligible to receive 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.

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.

*Milestone Payments*. Hammock is eligible to receive up to $250,000 in the aggregate upon achievement of a regulatory development milestone related to a non-bacterial vaginosis product.

*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.

***Pear Tree Acquisition and License Agreements***

In May 2018, we completed our acquisition of Pear Tree Pharmaceuticals, Inc., or Pear Tree. We acquired Pear Tree to secure exclusive, sublicensable, worldwide rights under certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration. This acquisition led to our DARE-VVA1 program. Under the merger agreement, former stockholders of Pear Tree are eligible to receive tiered royalties based on net sales of licensed products by us or our affiliates, subject to customary reductions and offsets and to offset by royalty and sublicense revenue share payments payable to Pear Tree's licensors as further described below, and a percentage of sublicense revenue. Former stockholders of Pear Tree and Pear Tree's licensors are also eligible to receive payments based on achievement of specified clinical development, regulatory and commercial milestones by licensed products as further described below.

*Milestone Payments*. Former stockholders of Pear Tree are eligible to receive up to $15.5 million in the aggregate in payments based on the achievement of clinical development and regulatory milestones by licensed products and up to $47.0 million in the aggregate in payments based on the achievement of commercial milestones by licensed products. These payments shall only be due once upon the first occurrence any of the specified milestone events. In addition, licensors of Pear Tree are eligible to receive up to approximately $3.2 million in the aggregate in payments based on the achievement of clinical development, regulatory and commercial milestones by each licensed product. These milestone payments may be made, in our sole discretion, in cash or in shares of our common stock in accordance with the terms of the merger agreement and the license agreements.

*Royalty Payments; Sublicense Revenue Share*. Former stockholders of Pear Tree are eligible to receive tiered royalties based on single-digit to low double-digit percentages of annual net sales of licensed products by us or our affiliates, subject to customary reductions and offsets, and a portion of royalties we receive from sublicensees. These payments may be made, in our sole discretion, in cash or in shares of our common stock in accordance with the terms of the merger agreement. Pear Tree's licensors are eligible to receive semi-annual royalties based on a single-digit percentage of net sales of licensed products by us or our affiliates, subject to customary reductions and offsets, or a portion of any royalties received by us or our affiliates from sublicensees, and a low double-digit percentage of all sublicensing fees or other lump sum payments or compensation we receive from sublicensees, subject to customary exclusions. Portions of certain milestone payments made to Pear Tree's licensors may be creditable against royalty payments due to Pear Tree's licensors.

*License Agreements Revenue Share Offset*. Under the merger agreement, in addition to customary royalty reductions and offsets, royalty payments and payments based on income received from sublicensees of licensed products made by us to Pear Tree's licensors are creditable against all royalty and sublicense revenue share payments payable to former stockholders of Pear Tree.

***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. As a result of this license agreement, we commenced our DARE-HRT1, DARE-FRT1 and DARE-PTB1 programs. We are entitled to sublicense the rights granted to us under this agreement.

*Annual Maintenance Fee.* We pay an annual license maintenance fee of $100,000 to Catalent on each anniversary of the date of the agreement, which will be creditable against royalties and other payments due to Catalent in the same calendar year (including milestone payments and sublicense income), but may not be carried forward to any other year.

*Milestone Payments.* Catalent is eligible to receive (1) up to $12.5 million in the aggregate in payments based on the achievement of specified clinical and regulatory milestones, and (2) up to $30.3 million in the aggregate in payments based on the achievement of specified commercial sales milestones for each product or process covered by the licenses granted under the agreement.

*Royalty Payments*. During the royalty term, Catalent is eligible to receive 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.

***Adare Development and Option Agreement***

In March 2018, we entered into an exclusive development and option agreement with Adare Pharmaceuticals USA, Inc. (formerly known as Orbis Biosciences, Inc., and which we refer to as Adare), for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which we refer to as DARE-204 and DARE-214, respectively). The agreement, as amended, provides us with an option to negotiate an exclusive, worldwide, royalty-bearing license, with rights to sublicense, for the programs if we fund the conduct of specified development work. We have no obligation to exercise our option.

***SST License and Collaboration Agreement***

In February 2018, we 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 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 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.

*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 $100.0 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.

***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 to develop and commercialize Ovaprene for human contraceptive use worldwide. We must use commercially reasonable efforts to develop and commercialize Ovaprene, and must meet certain minimum spending amounts per year, including $2.5 million per year to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first. ADVA-Tec will conduct certain research and development work as necessary to allow us to seek a PMA from the FDA. ADVA-Tec is responsible for providing us with clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, on commercially reasonable terms, and, except under limited circumstances, we may not obtain supplies of Ovaprene from another source.

Under the license agreement, in addition to an exclusive, sublicensable license to ADVA-Tec's and its affiliates' intellectual property rights for all uses of Ovaprene as a human contraceptive device, we have a right of first refusal to license these patents and patent applications for additional indications.

*Milestone Payments.* We may pay to ADVA-Tec: (1) up to $13.0 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 future development and regulatory milestones include: successful completion of a Phase 3/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.

*Royalty Payments.* ADVA-Tec is eligible to receive 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, subject to customary reductions and offsets.

*Sublicense Revenue Payments*. If we sublicense our rights under the license agreement, in lieu of royalty payments to ADVA-Tec, ADVA-Tec is eligible to receive a double-digit percentage of sublicense revenue received by us during the royalty term; provided, however, that for sublicense revenue we receive prior to the first commercial sale of a licensed product that represents an upfront payment or license fee due on or around the effective date of the sublicense, ADVA-Tec is eligible to receive a single-digit percentage of that sublicense revenue.

*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, or (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.

**Royalty Interest Financing Agreement**

In December 2023, we entered into a royalty interest financing agreement with United in Endeavour, LLC, or United, pursuant to which we sold to United an interest in the royalty and milestone payments we receive from Organon in respect of net sales of XACIATO. On the effective date of the agreement, we received a payment of $5.0 million, or the Initial Investment, from United. Until December 31, 2026, we may, at our sole discretion, elect to receive three additional payments of up to an aggregate of $7.0 million. We refer to each such payment as a Supplemental Discretionary Investment Amount, and collectively, as the Total Supplemental Discretionary Investment Amount.

We will make payments to United under the agreement until such time when United has received aggregate payments equaling a 12% internal rate of return, or the IRR, on the Initial Investment and the Total Supplemental Discretionary Investment Amount, if any (referred to as the Hard Cap). Until such time as the IRR has been achieved, we agreed to make payments to United equal to (i) from the date of the agreement through December 31, 2025, 50% of the amount of royalty payments remaining after all amounts that are due and payable and actually paid by us to any licensor or sublicensee on the royalty payments generated and received by us on net sales of XACIATO by Organon have been deducted (such payments referred to as the Net Royalty Payments), (ii) from January 1, 2026 through December 31, 2029, 75% of the Net Royalty Payments, and (iii) from the date of the agreement through December 31, 2029, 10% of the amount of milestone payments remaining after all amounts that are due and payable and actually paid by us to any licensor or sublicensee on the milestone payments generated and received by us on net sales of XACIATO by Organon have been deducted. After December 31, 2029, we will be required to make certain additional payments to United to the extent United has not received payments equaling the Hard Cap by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if United has not received payments equaling the Hard Cap by December 31, 2035 and we have other sources of assets or income besides XACIATO sufficient to complete such payments, we have agreed to pay United quarterly payments evenly divided over a two-year term, such that United will have obtained the IRR, taking into account all other payments received by United from us under the agreement. United's right to receive payments will terminate when United has received the Hard Cap.

We have the right, but not the obligation, at any time, to repurchase all of the interest from United at a repurchase price equal to the Hard Cap, calculated as of the date of we exercise such call option.

The agreement contains representations and warranties, covenants, indemnification obligations, and other provisions customary for transactions of this nature and will terminate on the date that is the earlier of (i) the date upon which the payment of the purchased interest in respect of XACIATO is made in full to United, and (ii) the payment to United of an aggregate amount equal to the Hard Cap.

In connection with the agreement, we issued to United a warrant to purchase up to 5.0 million shares of our common stock. In addition, for every $1.0 million of Supplemental Discretionary Investment Amount, we agreed to issue an additional warrant to purchase up to 1.0 million shares of our common stock, for an aggregate of additional warrants to purchase up to 7.0 million shares of our common stock.

The warrants are exercisable, in full or in part, at any time on or prior to the fifth anniversary of the date of issuance of the particular warrant at an exercise price of $0.3467 per share, subject to customary anti-dilution adjustments. The warrants may be exercised for cash, or if at the time of exercise there is no effective registration statement registering for resale the shares underlying the warrants, then in lieu of paying the exercise price in cash, the holder may elect to exercise the warrant on a cashless basis.

**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, regarding the thermosetting hydrogel platform which includes XACIATO, we are the exclusive licensee of three issued U.S. patents, two of which are set to expire in December 2028 and one of which is set to expire in September 2036, subject to any extensions or disclaimers, and three foreign patents, including one European Patent Office, or EPO, patent validated in four countries, that expire in December 2028, subject to any extensions or disclaimers, as well as two foreign patents, including one EPO patent validated in 22 countries, that expire in July 2036, subject to any extensions or disclaimers. One of the three issued U.S. patents is listed in the FDA’s compendium of “Approved Drug Products with Therapeutic Equivalence Evaluation," known as the Orange Book, under the Patent Exclusivity Information for XACIATO. In addition, we have rights to three pending foreign patent applications and one pending U.S. patent application. If issued, the patent term for any patents issuing from these pending applications would be expected to expire in 2036, subject to any extensions or disclaimers. We own a pending PCT application and one foreign application regarding XACIATO, and a pending PCT application directed to the thermosetting hydrogel platform. The patent term for any patents issuing from these pending applications would be expected to expire in 2042, subject to any extensions or disclaimers. Organon has licensed XACIATO-specific patents and applications from us.

Under the terms of the ADVA-Tec license agreement, regarding Ovaprene, we are the exclusive licensee of nine granted U.S. patents, one pending U.S. patent application, seven granted foreign patents, including four EPO

patents validated in a total of 55 countries, and four pending foreign patent applications. Two of the U.S. patents have terms until August 2028, which includes days added to the term by patent term adjustment, and a third patent has a term that expires in July 2027, including patent term adjustment, each of such terms being subject to any future extensions or disclaimers. The other U.S. and foreign patents are expected to expire in 2024, 2025, or 2026. The patent terms for any patents issuing from the pending applications would be expected to expire in 2035, subject to any extensions or disclaimers.

Under the terms of the SST license agreement, regarding Sildenafil Cream, we are the exclusive licensee in the Field of Use of 23 issued patents worldwide (10 U.S. patents and 13 foreign patents, including two EPO patents validated in a total of 20 countries). Additionally, there is one patent application pending in the US, one in Europe, and two in other international markets. The issued U.S. patents have a patent term that expires in June 2029, including any patent term adjustment, and may be eligible for regulatory exclusivity under the Hatch-Waxman Act, while several foreign patents have a term that is set to expire in late 2031, each of such terms being subject to any future extensions or disclaimers.

Under the terms of the Catalent license agreement, regarding our intravaginal ring platform which includes DARE-HRT1, we are the exclusive licensee of four issued U.S. patents with patent terms set to expire in April 2024, November 2024, February 2025, and September 2027, including patent term adjustment, four issued foreign patents with patent terms until April 2024, including one European patent validated in three countries, as well as one pending U.S. application and two pending foreign applications that if granted are expected to have patent terms that expire in May 2038, subject to any extensions or disclaimers. Additionally, relative to the DARE-HRT1 program, we are the sole owner of two pending U.S. provisional patent applications with an expected term, if granted, until 2044, subject to any extensions or disclaimers.

When we acquired Pear Tree Pharmaceuticals, Inc. in 2018, regarding DARE-VVA1, we obtained the rights to three U.S. patents and one Japanese patent. The patent terms for the U.S. patents are expected to expire in June 2027, June 2028, and May 2035 including any patent term adjustment, extensions or disclaimers. The Japanese patent has a term that is set to expire in June 2027. Additionally, relative to the DARE-VVA1 program, we are the sole owner of one pending U.S. provisional patent application with an expected term, if granted, until 2044, subject to any extensions or disclaimers.

When we acquired MBI in 2019, we obtained the rights to over 100 patents and applications. The key technology underlying the platform currently is supported by 14 U.S. patents and 49 foreign patents, including six EPO patents validated in various European countries, and 12 pending patent applications. We believe that the four most recently filed patent families are directly applicable to our DARE-LARC1 program. Those patent families have patent terms that are set to expire 2032, 2033, 2034, and 2040 respectively, subject to any extensions or disclaimers. Those patent families include patents granted in the U.S., E.U. and other key international markets.

Under the terms of the Hennepin license agreement, we are the exclusive licensee of five issued U.S. patents and four foreign patents, as well as four pending U.S. applications and twelve pending foreign applications. The U.S. patents are set to expire in 2025, 2026, 2028, 2033 and 2034 including any patent term adjustment, extensions or disclaimers, and the foreign patents have patent terms until 2025 or 2033. The U.S. and foreign applications, if granted, are expected to have patent terms that expire in 2033, 2037, 2038, and 2042, subject to any extensions or disclaimers.

Under the terms of the Douglas license agreement, we are the exclusive licensee of three granted U.S. patents and four pending U.S. patent applications. The granted patents are expected to expire in 2034 or 2039, including any patent term adjustment, extensions or disclaimers, and the U.S. applications, if granted, are expected to have patent terms that expire in 2039 and 2040.

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 and our registration for the XACIATO trademark in the U.S. is pending. In accordance with the terms of the ADVA-Tec license agreement, we are the exclusive licensee of the Ovaprene registered trademark.

**Competition**

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology and medical device) are highly competitive and subject to rapid and significant change. Our success is highly dependent upon our ability to acquire or in-license, develop and obtain regulatory approval for innovative medical products on a cost-effective basis and to market them successfully, either on our own or together with strategic partners. We face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies that already possess a significant share of the women's health market. 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 Commercialization of XACIATO and Our Product Candidates— Our product candidates, if approved, and XACIATO will face intense competition and our business and operating results will suffer if we, or our commercial collaborators, fail to compete effectively" and "— The women's health market includes many generic products and growth in generics is expected to continue, which could make the successful introduction of our branded products difficult and expensive" below.

XACIATO will compete directly with the multiple generic and branded prescription drug products currently approved in the U.S. for the treatment of bacterial vaginosis, including oral and vaginal gel formulations of metronidazole and vaginal cream formulations of clindamycin. Branded, single-dose FDA-approved products for bacterial vaginosis include Solosec® (secnidazole) oral granules manufactured for and distributed by Lupin Pharmaceuticals, Inc., Clindesse® (clindamycin phosphate) vaginal cream, 2% manufactured and distributed by Padagis, and Nuvessa™ (metronidazole vaginal gel 1.3%) distributed by Exeltis USA, Inc. Based on the XACIATO product profile reflected in the FDA-approved prescribing information, including the consistent cure rates demonstrated among the subsets of patients defined by prior episodes of bacterial vaginosis (≤ 3 and >3 episodes in the previous 12 months), and the labeling for special populations such as pregnant and lactating women, we expect that the product may to be used by health care providers as a first line option for treating bacterial vaginosis. As a result of our exclusive license agreement with Organon, the commercial success of XACIATO is largely outside of our control.

Our investigational contraceptive products, including Ovaprene, if approved, will compete with a wide range of prescription and over-the-counter contraceptive options, including hormone-free options such as condoms, diaphragms, cervical caps, sponges, copper IUDs, spermicides and vaginal gels, as well as hormonal products such as pills, patches, vaginal rings and injectables. In addition, multiple new methods of pregnancy prevention are in development, including hormone-free options, and some may be marketed in the U.S. before Ovaprene, potentially adding to the level of market competition Ovaprene will face, if approved.

Currently, there are no FDA-approved therapies for FSAD. Sildenafil Cream has the potential to be the first FDA-approved product for the treatment of FSAD.

DARE-HRT1, if approved as a treatment for moderate to severe VMS due to menopause, will compete with the many products on the market targeted or FDA-approved for the treatment of menopausal symptoms, including VMS. Such products include hormone therapies in the form of pills, patches and creams, some of which are FDA-approved products and others which are prepared in compounding pharmacies. We expect the options for hormone therapy to continue to expand with time. We believe DARE-HRT1 has the potential to address a preference among some women and health care providers for bio-identical hormones delivered in a non-oral route, as well as offer convenience compared to existing FDA-approved hormone therapies in that one IVR is designed to deliver the bio-identical hormones over 28 days without any daily intervention.

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., at the federal, state and local level, and other countries extensively regulate the research, development, testing, manufacturing, labeling and packaging, storage, recordkeeping, advertising, promotion, import, export, marketing, and distribution, among other things, of pharmaceutical, medical device, and drug-device combination products. The process of obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, require the expenditure of substantial time and financial resources.

We and our third-party manufacturers, distributors and contract research organizations, or CROs, may also be subject to government regulation under other federal, state, and local laws, including the U.S. Foreign Corrupt Practices Act, 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 comparable laws and regulations of other countries.

***U.S. Government Regulation***

In the U.S., the FDA, under the authorities granted to the agency by the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, subjects pharmaceutical and other regulated medical products to rigorous premarket review as well as post-marketing oversight and potential enforcement actions. Failure to comply with applicable U.S. requirements at any time during the product development or approval process, or after approval, may subject a company to a variety of administrative or judicial sanctions brought by the FDA and the Department of Justice, or DOJ, or other governmental entities, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending or future marketing applications;
- warning or untitled letters;
- withdrawal of an approval;
- imposition of a clinical hold;
- voluntary product recalls;
- seizures or administrative detention of product;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, civil penalties or criminal prosecution.

***FDA Approval Process for Prescription Drugs***

To obtain approval of a new drug product from the FDA, we must, among other requirements, submit extensive data supporting its safety and efficacy, as well as detailed information on the manufacture and composition of the drug and proposed product labeling and packaging. 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, such as laboratory tests, potentially animal studies, and formulation studies, performed in compliance with FDA regulations for good laboratory practices, or GLPs, and other applicable 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 according to good clinical practices, or GCPs, to establish the safety and efficacy of the product candidate for its intended use;
- submission of an NDA to the FDA along with payment of the application user fee 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 readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with current good manufacturing

practices, or cGMP, in order to assure that the facilities, methods and controls are adequate to preserve the drug candidate's identity, strength, quality and purity;

- possible inspection of selected clinical study sites to confirm compliance with GCP requirements and data integrity; and
- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, if applicable, which must occur prior to any commercial marketing or sale of the drug product in the U.S.

*Preclinical Studies*

After a therapeutic candidate is identified for development, it enters the preclinical or nonclinical testing stage. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA to specify that nonclinical testing for drugs may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests. Nonclinical tests intended for submission to the FDA to support the safety of a product candidate must be conducted in compliance with GLP regulations and the United States Department of Agriculture's Animal Welfare Act, if applicable. A drug sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will include one or more clinical protocols detailing, among other things, the objectives of the clinical trial and the safety and effectiveness criteria to be evaluated.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical study subjects.

*Human Clinical Trials in Support of an NDA*

The clinical investigation of an investigational new drug is divided into three phases that typically are conducted sequentially but may overlap or be combined. 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 healthy 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 candidate 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 candidate 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. Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed.

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. Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with the FDA's GCP requirements. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol, and any subsequent material amendment to the protocol, must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must report to the FDA serious and unexpected adverse reactions in a timely manner, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product or therapeutic candidate. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, via 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. An institutional review board, or IRB, is responsible for ensuring that human subjects in clinical studies are protected from inappropriate study risks. An IRB at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the trial until completed and otherwise comply with IRB regulations. The IRB also may halt a study, either temporarily or permanently, for failure to comply with GCP or the IRB's requirements, or if the investigational new drug has been associated with unexpected serious harm to patients.

During the development of a new drug product candidate, sponsors are given opportunities to meet with the FDA at certain points; specifically, prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the new therapeutic.

Post-approval trials, sometimes referred to as "Phase 4" clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of "Phase 4" clinical trials.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*Marketing Application Submission and FDA Review*

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. 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.

Under the Prescription Drug User Fee Act, or PDUFA, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for marketed prescription drug products. Fee waivers or reductions are available in certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the applicant is a small business submitting its first human therapeutic application for review.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from receipt in which to complete its initial review of a standard NDA for a drug that is not a new molecular entity, and six months from the receipt date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and the sponsor's process to respond to such inquiries. As a result, the NDA review process can be very lengthy. 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 traditional or "full NDA." In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. Section 505(b)(2) 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; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. 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 conducts a preliminary review of all NDAs it receives, whether submitted under Section 505(b)(1) or Section 505(b)(2), to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission, and 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 the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile and whether the product is being manufactured in accordance with cGMP. 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. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. 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 interprets the same data. The FDA may also re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

Before approving an NDA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving the NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements and to assure the integrity of the clinical data submitted to the FDA. To ensure cGMP and GCP compliance by its employees and third-party contractors, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

The FDA also may require the submission of a risk evaluation and mitigation strategy, or REMS, plan if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan. The FDA will not approve an NDA without a REMS plan, if required.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities where the drug product or its API will be produced and the clinical trial sites, the FDA will either issue an approval letter or, in some cases, a complete response letter, or CRL, that describes all of the specific deficiencies in the NDA identified by the agency. An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, the FDA nevertheless may ultimately decide that the NDA does not satisfy the regulatory criteria for approval.

Even if a drug product receives regulatory approval, the approval may be significantly limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as “Phase 4” clinical trials, designed to further assess a product’s safety and effectiveness, and/or testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

*Special FDA Programs to Facilitate and Expedite Development and Review of Certain New Drugs*

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include, but are not limited to, fast track designation, QIDP designation, and priority review designation. The purpose of these programs is to provide important new drugs to patients earlier than could occur under standard FDA procedures for interacting with and responding to product sponsors during development and regulatory review.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. A drug that is designated as a qualified infectious disease product (“QIDP”) is also eligible for fast track status. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process.

The Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, included the Generating Antibiotics Incentives Now Act, or the GAIN Act, which directed FDA to implement QIDP designation program. The GAIN Act created incentives for the development of antibacterial and antifungal drug products for the treatment of serious or life-threatening infections. A therapeutic candidate designated as a QIDP is eligible for fast track designation, and the first marketing application submitted for a specific drug product and indication for which QIDP designation was granted will be granted priority review. A subsequent application from the same sponsor for the same

product and indication will receive priority review designation only if it otherwise meets the criteria for priority review. As discussed further below under "New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension - Qualified Infectious Disease Product Exclusivity," the GAIN Act also provides the possibility of a five-year exclusivity extension that is added to any other marketing exclusivity for which a QIDP-designated drug qualifies upon FDA approval.

Finally, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, QIDP designation, and priority review do not change the standards for marketing approval and may not ultimately expedite the development or approval process.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

*Post-Approval Requirements for Prescription Drugs*

Following approval of a new drug product, the manufacturer and the approved drug are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Moreover, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or an NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. In particular, 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.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and some state agencies, and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other requirements. Changes to the manufacturing process, specifications or container closure system for an approved drug product are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the NDA sponsor and any third-party manufacturers involved in producing the approved drug product. Accordingly, both sponsors and manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance and other aspects of quality control and quality assurance, and to ensure ongoing compliance with other statutory requirements of the FDCA, such as the requirements for making manufacturing changes to an approved NDA.

Accordingly, even after a new drug approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or the imposition of distribution or other restrictions under a REMS plan. Other potential consequences of regulatory non-compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws. The Prescription Drug Marketing Act of 1987, or PDMA, was the first federal law to set minimum standards for the registration and regulation of drug distributors by the states and to regulate the distribution of drug samples. Today, both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. More recently, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, repackagers, wholesale distributors, and dispensers (primarily pharmacies) over a 10-year period that culminated in November 2023. It also replaced certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme, requiring uniform national standards for wholesale distribution and, for the first time, for third-party logistics providers. In February 2022, the FDA released proposed regulations to amend the existing national standards for licensing of wholesale drug distributors by the states (which had been promulgated under the PDMA); to establish new minimum standards for state licensing third-party logistics providers; and to create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA. Most recently, the FDA announced a one-year stabilization period to November 2024, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of prescription drug products regulated by the FDA.

***FDA Review and Approval of Medical Devices***

Medical devices also are strictly regulated by the FDA in the United States. Under the FDCA, a medical device is defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.” This definition provides a clear distinction between a medical device and other FDA-regulated products such as drugs. If the primary intended use of a medical product is achieved through chemical action or by being metabolized by the body, the product is usually a drug or biologic. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through the premarket notification, or 510(k), process, or approved by the FDA pursuant to a PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. As electronic and digital medical devices have become increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve health care and patient accessibility, FDA and other regulatory authorities have recognized that those same features also increase the risk of potential cybersecurity threats. These types of medical devices may be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device, and accordingly

device manufacturers are responsible for identifying cybersecurity risks and hazards associated with their products. In recent years, the FDA has increased its scrutiny of this issue as part of the review and marketing authorization process for new medical devices; the agency also monitors reports of cybersecurity risks as part of its post-marketing device surveillance activities. In addition, as part of the Consolidated Appropriations Act for 2023, Congress created new premarket requirements for developers of "cyber devices," defined as medical devices that include software, connect to the internet, and contain any technological features that could be vulnerable to cybersecurity threats.

Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably assure their safety and effectiveness. Class I devices are those low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR; facility registration and product listing; reporting of adverse medical events and malfunctions; and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Most Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) process.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for most Class II devices is accomplished through the 510(k) process, although some Class II devices are exempt from the 510(k) requirements. To obtain 510(k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent to a device that is already legally marketed in the United States and for which a PMA was not required (i.e., a Class II device). The device to which the sponsor's device is compared for the purpose of determining substantial equivalence is called a "predicate device." The FDA's goal is to make a substantial equivalence determination within 90 days of FDA's receipt of the 510(k) application, but it often takes longer if the FDA requests additional information. Most 510(k)s do not require supporting data from clinical trials, but such data is typically required if the predicate device relied in part on clinical trial data to obtain clearance. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly a pre-market approval. Premarket notifications are subject to user fees, unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk to patients, such as life-sustaining or life-supporting devices, devices that present a potential unreasonable risk of illness or injury, or, more generally, devices whose safety and effectiveness cannot be assured solely by the general controls and special controls described above. All Class III devices must be reviewed and approved by the FDA through the PMA process. A PMA must be supported by extensive data including, but not limited to, technical data, nonclinical studies, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is submitted and the FDA determines the application is sufficiently complete, the agency will accept it for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, it considers such recommendations when making final decisions on approval. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. New PMA applications or supplements are also required for product modifications that affect the safety and efficacy of the device. PMA (and supplemental PMAs) are subject to significantly higher user fees than are 510(k) premarket notifications.

Novel medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they ultimately pose to patients and/or users. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *De Novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II based on a benefit-risk analysis demonstrating the device actually presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of FDASIA, a medical device could only be eligible for *De Novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *De Novo* classification pathway by permitting manufacturers to request *De Novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not

substantially equivalent determination. The FDA is required under the statute to classify the device within 120 days following receipt of the *De Novo* application however, the most recent FDA premarket review goals state that in fiscal year 2023, FDA will attempt to issue a decision on 70% of all *De Novo* classification requests received within 150 days of receipt. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. *De Novo* classification requests are also subject to user fees, unless a specific exemption applies.

Clinical trials are almost always required to support a PMA application and are sometimes required for a *De Novo* classification request or 510(k) premarket notification. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, an investigator acting on behalf of the company must, among other things, apply for and obtain IRB approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the company sponsoring the investigation must also submit and obtain FDA approval of an IDE. An IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of study participants, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE is approved by the FDA and the study protocol and informed consent form are approved by a duly-appointed IRB at each clinical trial site. A diversity action plan will be required for most clinical studies of investigational medical devices intended to support marketing authorization as a result of the December 2022 FDCA amendments.

FDA's IDE regulations govern investigational device labeling, prohibit promotion, and specify an array of GCP requirements, which include, among other things, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

*Post-Marketing Requirements for Medical Devices*

After a medical device is placed on the market, numerous regulatory requirements apply that in some ways mirror the post-approval requirements for prescription drugs. These include, but are not limited to:

- submitting and updating establishment registration and device listings with the FDA;
- compliance with the QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- pre-scheduled or unannounced device facility inspections by the FDA;
- labeling regulations, which prohibit the promotion of devices for uncleared or unapproved (or "off-label") uses and impose other restrictions relating to promotional activities;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any distributed devices fail to meet established specifications, are otherwise misbranded or adulterated, or if any other material deficiency is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

As with prescription drugs, the failure to comply with applicable device regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA approvals of new or modified devices;
- withdrawals of marketing authorization; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, prescheduled or unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors and third-party component suppliers.

***FDA Review and Approval Process for Combination Products***

A combination product is a product composed of a combination of two or more FDA-regulated product constituent parts or products, e.g., drug-device or biologic-device. Such products often raise regulatory, policy and review management challenges because they integrate constituent parts that are regulated under different types of regulatory requirements and by different FDA Centers, namely, the Center for Drug Evaluation and Research, or CDER, the Center for Devices and Radiological Health, or CDRH, or the Center for Biologics Evaluation and Research, or CBER. Differences in regulatory pathways for each constituent part can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated constituent parts that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The FDA's Office of Combination Products, or OCP, was established to provide prompt determination of the FDA Center with primary jurisdiction over the review and regulation of a combination product; ensure timely and effective premarket review by overseeing the timeliness of and coordinating reviews involving more than one center; ensure consistent and appropriate post-market regulation; resolve disputes regarding review timeliness; and review/revise agreements, guidance and practices specific to the assignment of combination products.

OCP determines which Center will have primary jurisdiction for the combination product, referred to as the Lead Center, based on the combination product's "primary mode of action," or PMOA. A mode of action is the means by which a product achieves an intended therapeutic effect or action. The PMOA is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. The Lead Center has primary responsibility for the review and regulation of a combination product; however a second Center is often involved in the review process, especially to provide input regarding the "secondary" component(s). In most instances, the Lead Center applies its usual regulatory pathway. For example, a drug-device combination product assigned to CDER will typically be reviewed under an NDA, while a drug-device combination product assigned to CDRH is typically reviewed under through a 510(k), PMA, or *De Novo* classification request.

Often it is difficult for OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which Center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product. A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute, to obtain a binding decision as to which Center will regulate the combination product. If the sponsor objects to that decision, the sponsor may request that OCP reconsider its decision.

Combination products are subject to FDA user fees based on the type of application submitted for the product's premarket approval or clearance. For example, a combination product for which an NDA is submitted is subject to the NDA fee under PDUFA. Likewise, a combination product for which a PMA is submitted is subject to the PMA fee under the Medical Device User Fee and Modernization Act.

Since a combination product incorporates two or more constituent parts that have different regulatory requirements, a combination product manufacturer must comply with all cGMP and QSR requirements that apply to each constituent part. The FDA has issued a combination product cGMP regulation, along with final guidance, describing two approaches a combination product manufacturer may follow to demonstrate compliance. Under these two options, the manufacturer demonstrates compliance with: (1) All cGMP regulations applicable to each separate regulated constituent part included in the combination product; or (2) either the drug cGMP or the QSR, as well as with specified provisions from the other of these two sets of requirements (also called the "streamlined approach"). In addition, The 21st Century Cures Act, or the Cures Act, which became law in December 2016 and, among other things, amended provisions of the FDCA, clarified that for drug-device combination products with a device PMOA and an FDA-approved drug constituent part, Hatch-Waxman Act requirements apply. Accordingly, a potential patent dispute regarding the listed drug that is being referenced by the combination product sponsor may delay the marketing authorization of the combination product. Furthermore, the Cures Act amendments applied Hatch-Waxman Act exclusivity provisions (e.g., new chemical entity and new clinical investigation) to the device clearance and approval process for combination products with a device PMOA.

***New Drug Marketing Exclusivity under the Hatch-Waxman Act Amendments & GAIN Exclusivity Extension***

*Orange Book Listing & Patent Certification*

As noted above, Congress created the 505(b)(2) NDA pathway in 1984 as part of the Hatch-Waxman Act amendments to the FDCA. At the same time, it also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD. Unlike the ANDA pathway, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies to demonstrate safety or effectiveness of the proposed change(s) being made to a previously approved drug.

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in the Orange Book. Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant's product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or a 505(b)(2) NDA that relies in full or in part on the reference product.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the ANDA applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator's listed patents, FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA/505(b)(2) applicant.

*Non-Patent Exclusivity*

An ANDA or 505(b)(2) NDA also will not be approved until any applicable non-patent exclusivities listed in the Orange Book for the referenced product have expired. The Hatch-Waxman Act amendments to the FDCA provided a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of data exclusivity if an NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, an applicant submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

*Qualified Infectious Disease Product Exclusivity*

Under the GAIN Act amendments to the FDCA, the FDA may designate a product as a QIDP for a specific use for which it is being studied, upon the written request of a sponsor at any time prior to submission of a marketing application. In order to qualify for designation as a QIDP, the drug product candidate must qualify as an antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (i) an antibiotic or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (ii) a so-called "qualifying pathogen" found on a list of potentially dangerous, drug-resistant organisms established and maintained by the FDA. In addition to the expedited review benefits that a QIDP-designated drug candidate may be eligible for (described above under "Special FDA Programs to Facilitate and Expedite Development and Review of Certain New Drugs"), such a drug that is approved for the use for which the QIDP designation was granted will receive a five-year extension to any non-patent marketing exclusivity period for which the drug qualified upon approval, such as a five-year NCE exclusivity or three-year new clinical data exclusivity. This so-called GAIN exclusivity extension is not available to a QIDP-designated drug that has previously received the five-year extension period, such as when an applicant is seeking approval for a new indication or new strength for a marketed infectious disease product.

***Patent Term Extension***

A patent claiming a prescription drug or medical device for which FDA approval is granted may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug or medical device is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the marketing approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs and medical devices, are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against clinical trial sponsors that fail to comply with such requirements.

***Other U.S. Health Care Laws and Compliance Requirements***

As we plan to commercialize our product candidates, if approved, we are subject to additional health care statutory and regulatory requirements and enforcement by federal government and the states and foreign governments in the jurisdictions in which we conduct our business. Health care providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Arrangements we may enter into with third-party payors or other customers expose us to broadly applicable fraud and abuse and other health care laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval.

Violations of the fraud and abuse laws, or other health care laws, are punishable by criminal and civil sanctions, including, in some instances, the possibility of exclusion from participation in federal and state health care

programs, (including Medicare and Medicaid), and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called “responsible corporate officer” doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers, employees or consultants of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions under some of the fraud and abuse laws described below. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and extensive enforcement of them by law enforcement authorities. Further, federal and state laws that require manufacturers to make reports on pricing and marketing information could subject us to penalty provisions.

These applicable health care industry laws include, among others, health care information and data privacy and security laws, transparency laws, and fraud and abuse laws, such as:

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, providing, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with health care companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;
- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal, civil and criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- The Physician Payments Sunshine Act, enacted as part of the ACA (defined below), among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non-physician health care practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members in such manufacturers;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations impose specified requirements relating to the privacy, security and electronic exchange of individually identifiable health information (called "protected

health information" under HIPAA) as well as requirements for notification to affected individuals and the government in the event of a breach. Among other things, HITECH makes certain of HIPAA's privacy and all of HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of "covered entities," or organizations subject to HIPAA which include certain health care providers, health plans, and health care clearinghouses. Business associates create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and created penalties for third parties that unlawfully acquire protected health information. HITECH also gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions; and

- State and local laws which require the registration of pharmaceutical sales representatives.

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 expanding and complicating compliance requirements. 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.

To the extent we commercialize or co-promote our products, if approved, and because such products could be reimbursed under federal and other governmental health care programs, we have developed an appropriate compliance program, commensurate to the limited commercial activities in which we engage, 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. Ensuring that our current and future business arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other health care laws and regulations. Moreover, if any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

***Coverage, Pricing, and Reimbursement***

Sales of our drug and drug-device combination 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 prescription 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 prescription products among third-party payors in the United States; therefore coverage and reimbursement for prescription products can differ significantly from payor to payor.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment

rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. One third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Accordingly, 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 granted at all. 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. In August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA, which includes (among other things) multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drug products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are ongoing.

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. Individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that appears to be leading to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including medical product developers like us.

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. Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future.

It is uncertain whether and how future legislation or regulatory changes 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.

***Data Privacy and the Protection of Personal Information***

We are subject to numerous laws and regulations governing data privacy and the protection of personal information of patients, clinical investigators, employees, and vendors/business contacts including in relation to medical records and other health information, credit card data and financial information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy of health and personal information and federal and state consumer protections laws that regulate the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties as well as reputational harm. Our customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA, HITECH and state health information privacy laws. If we knowingly obtain protected health information without the authority to do so, our customers or research collaborators may be subject to enforcement and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act, or the FTC Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule. The FTC and states' Attorneys General have brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has adopted the California Consumer Privacy Act of 2018, or CCPA, which went into effect in January of 2020. The CCPA mirrors a number of the key provisions of the European General Data Protection Regulation, or GDPR, described below. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, requiring covered companies to provide new disclosures to consumers about such companies' practices for collection and use of consumer data, and providing customers new ways to opt-out of certain sales or transfers of personal information. In addition, the CCPA creates a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. More recently, a new privacy law, the California Privacy Rights Act, or CPRA, was approved by California voters in the election on November 3, 2020. The CPRA went into effect in January of 2023, modifying and strengthening the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which will be

enacting new regulations and will have expanded enforcement authority. Various states such as Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah and Virginia have enacted their own privacy laws similar to the CCPA, and other states are considering proposals for such.

***Health Care Reform and Potential Changes to Laws and Regulations***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates that receive marketing approval. FDA and other regulatory authority policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. In addition to the sweeping reforms contained in the ACA (summarized above in the section entitled “Coverage, Pricing, and Reimbursement”), other legislative changes have been proposed and adopted in the United States that may affect health care expenditures. In addition to the IRA's drug price negotiation provisions, discussed above, President Biden's Executive Order 14087, issued October 2022, called for CMS to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs. In February 2023, CMS published its report which described three potential models focusing on affordability, accessibility and feasibility of implementation for further testing by the CMS Innovation Center. As of February 2024, the CMS Innovation Center continues to test the proposed models and has started to roll out plans for access model testing of certain product types (e.g., cell and gene therapies) by states and manufacturers.

Other new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on customers for our approved product and, accordingly, our financial operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services. Moreover, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***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, if approved, either directly or through our distribution partners. 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, and the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. 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 therapeutic product candidate under European Union, or EU, 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 EU, such as countries in Eastern Europe, Latin America or Asia, and recently the United Kingdom, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may

negatively impact the regulatory process in others. Moreover, 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, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. 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.

International marketing and distribution of medical devices are also subject to foreign government regulations, which may vary substantially from country to country. There is a trend towards harmonization of quality system standards for medical device products among the European Union, United States, Canada and various other industrialized countries.

As of January 31, 2020, the United Kingdom is no longer a member state of the EU, and therefore a separate marketing authorization application and approval will be required to market a medicinal product in the U.K. The Medicines and Healthcare products Regulatory Agency is the U.K.'s standalone pharmaceutical and medical devices regulator.

***Review and Approval of Medicinal Products in the European Union***

As in the United States, medicinal products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Also similar to the United States, when a drug-device combination product's principal intended action is accomplished by the drug constituent part, the EU regulates the combination product as a medicinal product.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU had been implemented through national legislation of the member states. Under the previous system, an applicant obtained approval from the competent national authority of an EU member state in which the clinical trial was conducted. Furthermore, the applicant could only start a clinical trial after a competent ethics committee had issued a favorable opinion. In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted and became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal" called the Clinical Trial Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials. Use of the CTIS became mandatory for new clinical trial application submissions as of February 1, 2023.

To obtain marketing approval of a drug in the EU, an applicant must submit a marketing authorization application ("MAA") either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, Iceland, Lichtenstein and Norway. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of certain diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the European Medicines Agency ("EMA") is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use ("CHMP"). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

The decentralized procedure is available to applicants who wish to market a product in specific EU member states where such product has not received marketing approval in any EU member states before. The decentralized procedure provides for an applicant to apply to one-member state to assess the application (the reference member state) and specifically list other member states in which it wishes to obtain approval (concerned member states). Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labelling and package leaflet, to the reference member state and each concerned member state. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application which is then reviewed and approved commented on by the concerned member states. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

In the EU, only products for which marketing authorizations have been granted may be promoted. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Moreover, even if authorized to be marketed in the EU, prescription-only medicines may only be promoted to health care professionals, not the general public. All promotion should be in accordance with the particulars listed in the summary of product characteristics. Promotional materials must also comply with various laws, and codes of conduct developed by pharmaceutical industry bodies in the EU which govern (among other things) the training of sales staff, promotional claims and their justification, comparative advertising, misleading advertising, endorsements, and (where permitted) advertising to the general public. Failure to comply with these requirements could lead to the imposition of penalties by the competent authorities of the EU member states. The penalties could include warnings, orders to discontinue the promotion of the drug product, seizure of promotional materials, fines and possible imprisonment.

Prior to May 26, 2021, the date on which the new Medical Device Regulation ("MDR") became effective, medical devices marketed in Europe were required to comply with the Essential Requirements defined in Annex I to the EU Medical Devices Directive, or MDD, a coordinated system for the authorization of medical devices. The MDD regulated the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives. The method of assessing conformity depended on the class of the product, but normally involved a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product.

In 2017, European Union regulatory bodies finalized a new Medical Device Regulation ("MDR"), which provided three years for transition and compliance, for a final effective date of May 26, 2020. As a result of the COVID-19 pandemic, however, the implementation date was postponed by one year to May 26, 2021, and a further transition period until May 26, 2024 gives the medical device industry and Notified Bodies additional time to come into compliance. The MDR changed several aspects of the existing regulatory framework for medical device marketing in Europe and increased regulatory oversight of all medical devices marketed in the EU, which may, in turn, increase the costs, time and requirements that need to be met in order to place an innovative or high-risk medical device on the European market. Specifically, the MDR requires post-market clinical follow-up evidence for medical devices, annual reporting of safety information for Class III products, and bi-annual reporting for Class II products, unique device identification, or UDI, for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, reclassification of medical devices, and multiple other labeling changes. A CE certificate issued under the MDD before May 26, 2021 may remain valid until May 25, 2024 under certain conditions. Longer transition periods for various medical devices covered by certificates or declarations of conformity issued before May 26, 2021 were implemented by the European Commission in March 2023 in order to mitigate the risk of device shortages in the EU. The new transition periods permit devices certified in accordance with the MDD to remain on the market under such certifications until May 26, 2026 for class III implantable custom-made devices, December

31, 2027 for Class III and implantable class IIb devices, and December 31, 2028 for all other class IIb and lower risk devices. As a new market entrant, however, the transition provisions do not apply to our business and we must acquire approvals under the MDR for new products, which could be challenging and costly.

***Review and Approval of Medicinal Products in Canada***

Health Canada is the Canadian federal authority that regulates, evaluates and monitors the safety, effectiveness, and quality of drugs, medical devices, and other therapeutic products available to Canadians. Health Canada's regulatory process for review, approval and regulatory oversight of products is similar to the regulatory process conducted by the FDA. To initiate clinical testing of a drug candidate in human subjects in Canada, a CTA must be filed with and approved by Health Canada. In addition, all federally regulated trials must be approved and monitored by research ethics boards. The review boards study and approve study-related documents and monitor trial data.

Prior to being given market authorization for a drug product, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act (Canada) and its associated regulations, including the Food and Drug Regulations. This information is usually submitted in the form of a New Drug Submission, or NDS. Health Canada reviews the submitted information, sometimes using external consultants and advisory committees, to evaluate the potential benefits and risks of a drug. If after of the review, the conclusion is that the patient benefits outweigh the risks associated with the drug, the drug is issued a Drug Identification Number ("DIN"), followed by a Notice of Compliance ("NOC"), which permits the market authorization holder (i.e., the NOC and DIN holder) to market the drug in Canada. Drugs granted an NOC may be subject to additional postmarket surveillance and reporting requirements.

All establishments engaged in the fabrication, packaging/labeling, importation, distribution, and wholesale of drugs and operation of a testing laboratory relating to drugs are required to hold a Drug Establishment License to conduct one or more of the licensed activities unless expressly exempted under the Food and Drug Regulations. The basis for the issuance of a Drug Establishment License is to ensure the facility complies with cGMP as stipulated in the Food and Drug Regulations and as determined by cGMP inspection conducted by Health Canada. An importer of pharmaceutical products manufactured at foreign sites must also be able to demonstrate that the foreign sites comply with cGMP, and such foreign sites are included on the importer's Drug Establishment License.

Regulatory obligations and oversight continue following the initial market approval of a pharmaceutical product. For example, every market authorization holder must report any new information received concerning adverse drug reactions, including timely reporting of serious adverse drug reactions that occur in Canada and any serious unexpected adverse drug reactions that occur outside of Canada. The market authorization holder must also notify Health Canada of any new safety and efficacy issues that it becomes aware of after the launch of a product.

The Canadian regulatory approval requirements for new drugs outlined above are similar to those of other major pharmaceutical markets. While the testing carried out in Canada is often acceptable for the purposes of regulatory submissions in other countries, individual regulatory authorities may request supplementary testing during their assessment of any submission. Therefore, the clinical testing conducted under Health Canada authorization or the approval of regulatory authorities of other countries may not be accepted by regulatory authorities outside Canada or other countries.

Health Canada has also implemented a similar process as the FDA for regulating combination products comprising both drug and device constituent parts. The agency considers the principal mechanism of action by which the claimed effect or purpose of the product is achieved, and then subjects the entire product to regulation under either the Food and Drug Regulations or the Medical Devices Regulations.

*Rest of the World Regulation*

In addition to regulations in the United States, EU, and Canada, we may become subject to a variety of regulations governing clinical studies and commercial sales and distribution of prescription drug and drug-device combination products in other jurisdictions around the world. These laws and regulations typically require the licensing of manufacturing and contract research facilities, carefully controlled research and testing of product candidates and governmental review and approval of results prior to marketing therapeutic product candidates. Additionally, they may require adherence to the FDA's GLPs, GCPs, and cGMPs during manufacturing. The process of new drug approvals

by regulators in the United States, Canada and the European Union are generally considered to be among the most rigorous in the world.

Whether or not FDA, EMA, or Health Canada approval is obtained for a product, we must obtain approval from the comparable regulatory authorities of other countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for the FDA, EMA, or Health Canada approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In some international markets, additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

Moreover, outside of the United States, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. In some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

***Europe – Data Privacy***

On May 25, 2018, the GDPR went into effect, implementing a broad data protection framework that expanded the scope of EU data protection law, including to non-EU entities that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of European Union-based data subjects including: providing expanded disclosures about how their personal data will be used; limitations on retention of personal data, higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; requirements to conduct data protection impact assessments for "high risk" processing; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be “forgotten” and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as “special category” data under the GDPR and afforded greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions – including restrictions – on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the EU member states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states’ laws and regulations, including where permitted derogations from the GDPR are introduced.

We will also be subject to evolving EU laws on data export, if we transfer data outside the EU to ourselves or third parties outside of the EU. The GDPR only permits exports of data outside the EU to countries deemed by the European Commission to have adequate data privacy laws or where there is a suitable data transfer solution in place to safeguard personal data (e.g. the European Union Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the European Union or the CJEU, issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II*. This decision a) calls into question certain data transfer mechanisms as between the EU member states and the U.S. and b) invalidates the EU-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the U.S.

On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the *Schrems II* decision. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the U.S. along with its adequacy decision. Adequacy decisions can be adapted or even

withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under the GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the transfer of personal data from the EU to us in the United States will require greater scrutiny and assessments as required under *Schrems II* and may have an adverse impact on cross-border transfers of personal data, or increase costs of compliance.

The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. We will be subject to the GDPR when we have a European Union presence or "establishment" (e.g., EU based subsidiary or operations), when conducting clinical trials with EU based data subjects, whether the trials are conducted directly by us or through a vendor or partner, or offering approved products or services to EU-based data subjects, regardless of whether involving a EU based subsidiary or operations.

***U.S. Foreign Corrupt Practices Act***

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain health care professionals in many countries, either directly or through third parties. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

***Environmental, Health and Safety Regulation***

We are subject to numerous federal, state and local environmental, health and safety, or EHS, laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our research laboratories. Some of these laws and regulations also require us to obtain licenses or permits to conduct our operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development and manufacturing activities involve use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure that EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

**Employees**

As of March 27, 2024, we had 26 employees. Twenty three of our employees are full-time and three are part-time, 18 are in research and development and eight are 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 employee base. We believe this approach enables 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. In the future, if we select a commercialization strategy for a product candidate that requires us to establish marketing, sales or distribution infrastructure and capabilities, we may need to rapidly increase our employee base.

**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.” and began to focus on development of innovative, investigational products in women's health. 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**

**Summary of Risk Factors**

*Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. We urge investors to carefully review and consider the additional discussion of the risks summarized in this risk factor summary, and other risks that we face, which can be found below under the heading "Risk Factors," together with other information in this report, before making investment decisions regarding our securities.*

- We will need to raise substantial additional capital to continue our operations, execute our business strategy and remain a going concern, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all. Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights in our technologies or product candidates and their future revenue streams.
- 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 and substantial capital requirements, make it difficult to assess our prospects.
- Our business depends on obtaining the approval of regulatory authorities, and in particular, FDA approval, to market products that we develop. All of our product candidates are investigational, require the conduct and successful completion of clinical studies and nonclinical work, and may never complete development or be submitted for or receive regulatory approval. The FDA's approval of XACIATO is not predictive of favorable development or marketing approval outcomes for our product candidates.
- Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully complete clinical trials and nonclinical activities and obtain regulatory approval to market and sell our product candidates on our anticipated timelines at reasonable costs to us, or at all, particularly Ovaprene and Sildenafil Cream, could have a material adverse effect on our business, operating results and financial condition.
- The regulatory approval processes of the FDA and comparable foreign authorities are expensive, lengthy, time-consuming, and inherently unpredictable. If we are not able to obtain regulatory approvals for our product candidates, our ability to generate product revenue will be materially impaired.
- Drug products and drug/device combination products are complex to manufacture and we face significant challenges in scaling up manufacturing of our product candidates for larger clinical trials and commercial production. Manufacturing and supply delays and disruptions could postpone the initiation of or interrupt our clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and adversely impact the commercialization of any approved products.
- Strategic collaborations are a key part of our strategy and our existing strategic collaborations are important to our business. If we are unable to maintain existing strategic collaborations or establish new ones, or if they are not successful, we may require substantial additional capital to develop and commercialize our products and product candidates and our business and prospects may be materially harmed.
- Unless and until one of our product candidates receives regulatory approval, payments under our license agreement with Organon based on net sales of XACIATO represent our only potential source of ongoing revenue and the amount of those net sales is largely outside of our control.
- We have no manufacturing, sales, marketing or distribution infrastructure. We depend heavily on, and expect to continue to rely on, the performance of third parties, including our strategic collaborators, contract manufacturers and suppliers, CROs, medical institutions, and scientific, medical, regulatory and other consultants and advisors, to develop our product candidates and commercialize any approved products. Failure of these third parties to perform as expected could result in substantial delays, increased costs or failures of our product development programs, delayed or unsuccessful commercialization of any approved products, and the need for significant additional capital.
- Due in part to our limited financial and human resources, we may fail to effectively execute our product development, regulatory submission and commercialization plans in accordance with communicated timelines, or at all.

- The loss or impairment of our rights under our license agreements for XACIATO or any of our product candidates could prevent us from developing or commercializing them, which could have a material adverse effect on our business prospects, operations and viability.
- The commercial success of XACIATO will depend on Organon's efforts and capabilities and a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our reputation, business and prospects may suffer.
- XACIATO and any future products will face intense competition, including from generic products, and may fail to achieve the degree of market acceptance necessary for commercial success. Our business, operating results and financial condition will suffer if we, or our commercial collaborators, fail to compete effectively and fail to achieve market acceptance.
- Failure to successfully obtain coverage and adequate reimbursement for XACIATO and any future products from government health care programs and other third-party payors would diminish our ability, or that of a commercial collaborator, to generate net product revenue or net sales. If out-of-pocket costs for products we develop are deemed by women to be unaffordable, a commercial market may never develop.
- We have a relatively small number of employees, and if we fail to attract and retain key personnel or effectively manage our personnel costs, our business may materially suffer.
- We may not be successful in our efforts to identify and acquire or in-license additional product candidates or technologies, which may limit our growth potential.
- Our failure to adequately protect or enforce our intellectual property rights, and those of our licensors, could materially harm our proprietary position in the marketplace or prevent or impede the commercialization of XACIATO and any future products.
- Lack of patent protection for the active ingredients in certain of our product candidates, including Sildenafil Cream and DARE-HRT1, may limit the commercial opportunity for those products if competitors are able to develop and commercialize safe and effective alternative formulations or methods of delivery of the active ingredients.
- Volatility in the financial markets, geopolitical conflicts and events, public health emergencies such as the COVID-19 pandemic and other macroeconomic factors may negatively impact our business, financial condition and results and our stock price, including by increasing the cost and timelines for our clinical development programs or making it more difficult or costly to raise additional capital when needed.
- Product liability lawsuits against us could cause us to incur substantial liabilities and divert management attention from our business.
- The price of our common stock has been and may continue to be highly volatile and such volatility may be related or unrelated to our performance and operating results. Volatility in our stock price may subject us to increased risk of securities litigation, including class-action lawsuits, which could be expensive and divert management attention.
- If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.
- Future dilution to our existing stockholders from sales and issuances of our common stock through at-the-market, or ATM, offerings, other types of public or private offerings of equity or equity-linked securities and upon the exercise of stock options, or the market's expectation that such sales could adversely affect our stock price, even if our business is doing well.
- We have been subject to a cyber-related crime and our controls and security measures may not be successful in preventing other cybersecurity incidents in the future. Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our strategic collaborators or third-party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information, subject us to significant financial loss, or expose us to liability, any of which could adversely affect our business and our reputation.

**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 Financial Position and Capital Needs**

***We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.***

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 the foreseeable future as we develop and seek to bring to market our existing product candidates and as we seek to potentially acquire or license and develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2023 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. At December 31, 2023, our accumulated deficit was approximately $171.2 million, our cash and cash equivalents were approximately $10.5 million, our deferred grant funding liability under our grant agreements related to DARE-LARC1 and DARE-LBT was approximately $13.7 million, and our working capital deficit was approximately $2.9 million. Our cash and cash equivalents at December 31, 2023 represented funds received under such grant agreements and such funds may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. We will require additional capital to fund our operating needs into the third quarter of 2024. and to meet our current obligations as they become due. Advancing our investigational women's health products through clinical development and pursuing regulatory approval and commercialization will require substantial additional investment. We will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. The amount and timing of our capital needs have and will continue to depend highly on many factors, as discussed further below as well as under "ITEM 7. MANAGEMENT'S DISCUSSION OF AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS—Liquidity and Capital Resources—Plan of Operations and Future Funding Requirements."

Our management may devote significant time and we may incur substantial costs in pursuing, evaluating and negotiating potential capital-raising transactions and those efforts may not prove successful on a timely basis, or at all. If we cannot raise adequate additional capital when needed, we may be forced to reduce, or even terminate our operations. We may delay, scale back or eliminate one or more of our product development programs; relinquish rights under our license agreements with third parties relating to our product candidates; forgo opportunities to expand our product portfolio; take other measures to reduce our expenses; reorganize or merge with another entity; or file for bankruptcy 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 our stockholders may lose all or part of their investment in our common stock.

Our capital needs have depended on, and will continue to depend on, many factors that are highly variable and difficult to predict, including:

- the product development programs we choose to pursue;
- the cost and pace of preclinical and clinical development;
- the results of preclinical activities and clinical trials;
- the cost and timing of obtaining clinical supplies of product candidates;
- the cost and timing of regulatory submissions and decisions by the FDA and other regulatory authorities on our applications to commence and advance clinical development of and to market our product candidates;
- the amount and timing of payments to third parties required under acquisition, in-license and other agreements relating our rights to develop and commercialize our product and product candidates;
- the cost and timing of commercialization activities we undertake or engage third parties to undertake for any approved product;

- the amount and timing of future royalty, milestone or other payments, if any, we receive under our commercial collaboration agreements for XACIATO and Ovaprene;
- our ability to maintain, and establish new, strategic collaborations relating to the development and/or commercialization of our product and product candidates;
- the extent to which we acquire, in-license, or otherwise invest in new product candidates or technologies and the terms of any such transaction; and
- the cost and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights.

Should we add product candidates to our portfolio, should our existing product candidates require testing or other capital-intensive development activities that we do not anticipate, should the duration of our clinical trials be longer than anticipated, should manufacturing and supply be disrupted, or should regulatory approvals be delayed, our cash resources will be further strained. Should our product development efforts succeed, we will need to develop a commercialization plan for each product, which may also require significant resources to create and implement. In addition, the terms of any collaboration agreements for development and/or commercialization of our product and product candidates may significantly impact our need for additional capital. Because of these uncertainties and the other risks and uncertainties discussed in this “Risk Factors” section, we cannot reasonably estimate the amount funding necessary to successfully complete development of and seek regulatory approval for our product candidates or to commercialize any approved products. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our planned operations.

We may seek to raise additional capital through a variety of means, including equity, equity-linked or debt securities offerings, government or other grant funding, strategic collaborations or alliances, debt, royalty monetization or other structured financings, or other similar types of arrangements. Our past success in raising capital through equity offerings, grant funding, collaboration agreements, and a royalty monetization financing should not be viewed as an indication we will be successful in raising capital through those or any other means in the future. We expect that our ability to raise additional capital and the amount of capital available to us will depend not only on progress we and our collaborators make toward successfully developing, obtaining regulatory approval for and commercializing our product and product candidates, but also on factors outside of our control, such as macroeconomic and financial market conditions. To the extent we seek to obtain additional capital before achieving clinical, regulatory and/or sales milestones or when our stock price or trading volume or both are low, or when the general market for biopharmaceutical or women’s health companies is weak, additional capital may not be available to us on favorable terms, or at all.

Unstable and unfavorable market and economic conditions may harm our ability to raise additional capital. The occurrence or continued occurrence of macroeconomic factors or events similar to those experienced in recent years, such as a U.S. economic crisis or recession or recessionary concerns, inflation, public health emergencies (such as the COVID-19 pandemic), geopolitical conflict (such as the wars in Ukraine and the Middle East), natural/environmental disasters, supply-chain disruptions, terrorist attacks, strained relations between the U.S. and a number of other countries, social and political discord and unrest in the U.S. and other countries, and government shutdowns, among others, increase market volatility and have long-term adverse effects on the U.S. and global economies and financial markets. Volatility and deterioration in the financial markets and liquidity constraints or other adverse developments affecting financial institutions may make equity or debt financings more difficult, more costly or more dilutive and may increase competition for, or limit the availability of, funding from other third-party sources, such as from strategic collaborations and government and other grants.

***Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights in our technologies or product candidates and their future revenue streams.***

As discussed above, we may seek to raise additional capital through a variety of means. Raising capital through the issuance of shares of our common stock, or securities convertible into or exercisable for our common stock, may depress our stock price and substantially dilute our existing stockholders. The terms of securities issued may include liquidation or other preferences that may materially adversely affect the rights of our existing stockholders. Debt and other structured financings, if available, would increase our fixed payment obligations and may involve covenants requiring us to maintain specified financial ratios or a specified cash balance, or limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, or impose other operating restrictions that could adversely impact our ability to operate our business and pursue our strategic objectives. We could also be required to

meet certain milestones in connection with a debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies, product candidates or products, or otherwise agree to terms unfavorable to us. In addition, we may be required to relinquish valuable rights to future revenue streams, such as in the case of the royalty interest financing agreement we entered into in December 2023. Moreover, the lower our cash balance when we seek to raise additional capital, the more difficult, costly or dilutive to our existing stockholders it may be for us to raise additional capital.

We may be required to seek additional capital through arrangements with collaborators at an earlier stage of development or commercialization of our technologies, product candidates or products than otherwise would be desirable, in which case we may grant rights to our technologies, product candidates or products on terms that may not be as favorable to us or grant rights that we would otherwise prefer to retain. If we raise capital through new collaborations, strategic alliances or other similar types of arrangements, we may relinquish valuable rights to future revenue streams. Licensing agreements likely would significantly reduce our control over the development or commercialization of the licensed technology, product candidates or products, and our collaborators may become unable or unwilling to devote adequate resources to realize their full potential value. If we obtain funding through grants from governmental entities or private organizations, such parties may impose restrictions on our rights to technologies, product candidates or products developed with such funding, obtain rights to license such technologies, product candidates or products to third parties (e.g., if we are unable or unwilling to commercialize a product or make it available to certain patient populations in a timely manner or at certain prices), or require future royalty or other payments if such technologies, product candidates or products are commercialized.

***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 and substantial capital requirements, make it difficult to assess our prospects.***

We have a limited operating history upon which to evaluate our business and prospects. The development of drug and drug/device combination products in order to obtain regulatory approval is a highly speculative, lengthy and expensive undertaking and involves substantial risk. We cannot accurately determine the duration and completion costs of our development programs, or if, when and to what extent we will generate revenue from the commercialization of any of our product candidates. Other than XACIATO, which was recently commercially launched by our collaborator Organon, 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 do not expect the potential milestone and royalty payments to us under our exclusive license agreement for XACIATO will be sufficient to cover our operating expenses. We have not been profitable since we commenced operations and may never achieve profitability. We devote significant resources to licensing or otherwise acquiring the rights to our product candidates and to research and development, or R&D, activities for them. Since inception, we have incurred significant operating losses. As discussed above, we must raise additional capital to finance our operations and remain a going concern and adequate additional capital may not be available to us on a timely basis, or at all.

***If one of our commercial collaborators terminates its exclusive license agreement with us, our need for additional capital may significantly increase.***

We have entered into an exclusive license agreement with Organon for the commercialization of XACIATO and an exclusive license agreement with Bayer for the commercialization of Ovaprene, if approved. Each of these license agreements may be terminated by the licensee for convenience upon the completion of a specified notice period, subject to limited restrictions. Furthermore, under our agreement with Bayer, Bayer has no 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 by making a $20.0 million payment to us. If we do not successfully complete a pivotal clinical trial 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 elect not to make the license grant effective regardless of the outcome of the pivotal clinical trial. If an exclusive license agreement is terminated early, or in Ovaprene's case, does not become fully effective, we may realize only a small fraction of the potential value of the agreement to us, and we would need to raise significant additional capital to pursue further development and commercialization of XACIATO or Ovaprene, as applicable, or establish another commercial collaboration, which we may not be able to do on a timely basis, on favorable terms, or at all.

***The royalties we may receive under our license agreements with our commercial collaborators are based on net sales, which will be largely outside of our control.***

We expect XACIATO’s and Ovaprene’s value to us under our license agreements with Organon and Bayer, assuming the license grant to Bayer becomes effective, to be generated primarily through royalties and potential commercial milestone payments, in each case, based on net sales. The amount of net sales our products may

generate, if any, is largely outside of our control because marketing and sales activities will be conducted by the licensee and the product pricing will be determined by the licensee. Gross sales can be greatly reduced by sales discounts and allowances, which will also be determined by the licensee (or mandated by governmental entities) and outside of our control. Sales discounts may be particularly substantial for new products compared to established products to incentivize purchases and promote customer loyalty. These factors would serve to reduce our royalties and delay potential achievement of commercial milestones. If a commercial collaborator has no or limited commercialization success, or net sales are otherwise minimal due to pricing and discount structures, our operating results would be negatively impacted and our need for additional capital could significantly increase or be accelerated.

In the future, we may rely on revenues received from third-party licensees to fund our operations, and failure to receive such revenues, or receipt of only minimal revenue, may cause us to, among other things:

- pursue raising additional funds through equity or debt financings that could be dilutive to our stockholders or involve restrictive covenants, operational restrictions and security interests in our assets;
- enter into new strategic collaborations that may be less favorable than those we would have obtained under different circumstances;
- delay, reduce or terminate one or more development programs;
- reduce headcount;
- forgo opportunities to expand our product portfolio; or
- take other measures to reduce our expenses, pursue strategic transactions, such as a merger or other business combination or sale of assets, file for bankruptcy, or cease operations.

***We have relied heavily on sales of our common stock to fund our operations, and our future ability to obtain additional capital through stock sales or other securities offerings may be more costly or dilutive to our stockholders than in the past, or may not be available to us at all. Our ability to raise additional capital may be limited by a low trading volume, stock price and market capitalization, as well as by laws, regulations and market conditions.***

We have relied heavily on our ability to raise capital by selling shares of our common stock. For example, we raised an aggregate of approximately $79.1 million in gross proceeds in fiscal years 2021 and 2022 through the sale of shares of our common stock in offerings made under a Form S-3 “shelf” registration statement. Our ability to raise additional capital through sales of our common stock or other securities offerings will depend on several factors, many of which may not be in our favor, including the trading volume and volatile trading price of our common stock, our relatively low public float and market capitalization, our potential inability to regain and maintain compliance with the listing requirements of the Nasdaq Capital Market, unfavorable financial market conditions, and the other risks and uncertainties described in this “Risk Factors” section. If we are unable to raise additional capital through the offering and sale of shares of our common stock, or securities convertible into or exercisable for our common stock, on a timely basis or acceptable terms, or at all, we may seek additional capital through other third-party sources that require us to relinquish valuable rights in our intellectual property, technologies, product candidates or future revenue streams, or that subject us to restrictive covenants, operational restrictions or security interests in our assets, or we may need to delay, scale back or eliminate some or all of our development programs, reduce other expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Using a shelf registration statement to conduct an equity offering 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 a shelf registration statement 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 our public float, was less than $75.0 million at the time of filing this annual report on Form 10-K, calculated in accordance with SEC rules. This means that we may use our 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 27, 2024, we could not offer or sell more than approximately $19.0 million of new securities under our shelf registration statement. If our ability to offer securities under an effective shelf registration statement is limited, including by the baby shelf rule, we may choose to conduct an offering of our securities under an exemption from registration under the Securities Act or under a Form S-1 registration statement.

We would expect either of these alternatives to take more time and be a more expensive method 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—If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock,” 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. Even if 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.

Obtaining stockholder approval is a costly and time-consuming process. If we must obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our business plan, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

***Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, 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 and pursue regulatory approvals 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 our efforts to develop and bring to market the product candidates currently in our portfolio and any candidates we may add to our portfolio in the future. Due to our limited resources, we have curtailed, and may be required to further curtail, our development programs and clinical and nonclinical development activities that might otherwise have led, or lead, to more rapid progress in the development of our product candidates, or product candidates that we may in the future choose to develop. 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, personnel 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.

As a result of financial and other resource constraints, we may be unable to commence or complete our planned clinical trials or prepare and submit applications for marketing approval of our product candidates in accordance with our currently anticipated timelines. See also “Risks Related to Product Research & Development, and Regulatory Approval – Delays in the commencement or completion of clinical testing of product candidates we

are developing or may develop in the future 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.

***Our cash could be adversely impacted if a financial institution with which we have deposit or other accounts fails.***

Our cash and cash equivalents we use to satisfy our working capital and operating expense needs are held in accounts at various financial institutions. The balance held in deposit accounts often exceeds the Federal Deposit Insurance Corporation ("FDIC") deposit insurance limit or similar government deposit insurance schemes. Our cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which we hold our cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation and taken into receivership by the FDIC. At that time, substantially all of our cash and cash equivalents were held in accounts with Silicon Valley Bank and we could not access such accounts. While we were afforded full access to our accounts on March 13, 2023 as a result of action taken by the U.S. Department of the Treasury, the Federal Reserve and the FDIC under the systemic risk exception, there is no guarantee that the systemic risk exception will be relied upon to provide access to uninsured deposits and other assets in the future in the event of the closure of a financial institution, or that such access would be afforded in a timely fashion. Any loss of our cash or cash equivalents or any delay in our access thereto could, among other risks, adversely impact our ability to pay our operating expenses, result in breaches of our contractual obligations, or result in violations of federal or state wage and hour laws if we are unable to pay our employees on a timely basis.

***Women's health has historically been an underfunded sector. Recently, a number of public companies focused in women's health have failed to achieve expected commercial success and struggled to access sufficient capital. We are solely focused in women's health and may be unfavorably impacted by weak investor sentiment and a lack of interest in the category. Our ability to access capital and to advance our candidates could be adversely impacted.***

We are solely focused in women's health, and primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility. The sector has historically been underfunded, with only about one percent of healthcare research and innovation in the U.S. invested in female-specific conditions beyond oncology according to market research. The failure of the women's health sector to receive consistent and committed investment fuels investor sentiment that market opportunities for new products in women's health are limited. Our stock price and our ability to access additional capital on acceptable terms when needed may be adversely impacted by unfavorable investor perception of market opportunities for women's health products, and our business, operating results, financial condition and prospects could suffer.

**Risks Related to Product Research & Development and Regulatory Approval**

***XACIATO is our first and only FDA-approved product. The FDA's approval of XACIATO does not provide any assurance or predict that we will be successful in developing or achieving regulatory approval of any other product candidate. If we are unable to successfully conduct and complete development of and obtain regulatory approvals for our investigational products, which may never occur, our business may fail and you could lose all or part of your investment.***

Historical success in clinical development of and obtaining regulatory approval for a product candidate does not guarantee or predict future successful outcomes for other investigational products. Each of our development programs is unique and subject to substantial uncertainty of success inherent in pharmaceutical and biopharmaceutical development.

Our pipeline consists entirely of investigational products, which we also refer to as product candidates, which means that they must successfully complete one or more clinical studies to be considered for marketing approval and undergo a submission and review process with the FDA to obtain approval to be marketed in the U.S., or a similar process with comparable regulatory authorities in other jurisdictions to be marketed anywhere outside of the U.S. FDA or other regulatory authority approval may never be obtained. If we are unable to successfully complete development of and obtain regulatory approvals for our product candidates, our business may fail and you could lose all or part of your investment.

***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 our product candidates, and in particular, Ovaprene and Sildenafil Cream, would likely adversely affect our business.***

Our business depends on the successful clinical development and regulatory approval of our product candidates, and in particular, our lead product candidates, which may never occur. The product candidates we develop require substantial clinical testing to demonstrate that they are safe and effective for their proposed uses. 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 some of our product candidates have undergone clinical trials and demonstrated positive results, including Ovaprene and Sildenafil Cream, there is no guarantee of successful outcomes in current or future clinical studies of these product candidates or of obtaining marketing approval for any of them. For example, while PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness and our PCT clinical trial of Ovaprene met its primary endpoint, there is no guarantee Ovaprene will demonstrate contraceptive effectiveness in its ongoing pivotal Phase 3 clinical study. As another example, while we believe the objectives of our exploratory Phase 2b RESPOND study of Sildenafil Cream were met and enabled successful completion of an end-of-Phase 2 meeting with the FDA and alignment on key elements of the Phase 3 program for Sildenafil Cream, the co-primary efficacy endpoints of the Phase 2b study were not met and there is no guarantee that Phase 3 clinical studies will be successful. The fact that the active pharmaceutical ingredients in certain of our product candidates, including Sildenafil Cream, received regulatory approval in other formulations and/or for other indications does not guarantee successful development of our product candidates for their proposed intended uses. Clinical trials may never demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates.

Even if we conduct and complete clinical trials for our product candidates, we may not obtain regulatory approval to market and sell any of them on the timelines we anticipate, or at all, which would have a material adverse effect on our business and operations.

***Outcomes of our clinical trials, particularly later-stage clinical trials, may significantly impact our stock price. If the results of our pivotal Phase 3 clinical study of Ovaprene are not positive, our stock price could decline and our business and prospects may be adversely affected.***

Ovaprene is one of our lead product candidates. If the results of our pivotal Phase 3 clinical study of Ovaprene are not positive or are perceived by third parties, including financial market participants, as not positive, our business, prospects and stock price could suffer significantly. If Ovaprene fails to demonstrate adequate safety or contraceptive effectiveness in the Phase 3 study, we may determine to delay, scale back or terminate the program, and we may not realize any return on our investment in the program. In addition, if we, the investment community, potential collaborators or the FDA view the topline or complete results of the study as not positive, our stock price could decline significantly, our reputation may suffer, and our ability to raise additional capital to continue to operate as a going concern and execute our business strategy could be adversely impacted.

***Delays in the commencement or completion of clinical testing of our product candidates 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.***

Clinical trials of our product candidates may not commence, progress or be completed as expected. 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 development activities for 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 those statements are predictions based on significant assumptions and the actual timing of achievement of development milestones may differ materially from our predictions for a variety of reasons.

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

- lack of adequate capital and the need to obtain additional funding;
- delays in obtaining guidance or authorizations from the FDA or foreign regulatory authorities;
- delays in obtaining approval from the institutional review boards, or IRBs, of prospective clinical study sites;

- delays in finalizing the trial design as a result of discussions with the FDA, foreign regulatory authorities, prospective clinical trial investigators or IRBs;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites; or
- inability to obtain sufficient quantities of clinical product supplies from our contract manufacturers and suppliers.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us, an IRB, the FDA or other regulatory authorities as a result of the occurrence of any of a number of events or circumstances, including:

- lack of adequate capital and the need to obtain additional 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 participants to use the investigational 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 undesirable side effects or other unexpected adverse events related to the investigational product;
- disruptions in or insufficient supply of clinical trial material or inadequate quality of such materials;
- failure of our CROs or other third-party service providers to meet their contractual obligations to us in a timely manner, or at all; or
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

Unexpected serious adverse events or other undesirable side effects could arise during clinical development and interrupt, delay, or cause the termination of clinical trials, and require us to conduct additional clinical and nonclinical studies that were not part of our development plan, which could significantly increase the development costs and timeline for a program and adversely impact its value and our ability to continue product development. These events may also cause our reputation to suffer and subject us to lawsuits.

As discussed elsewhere in this Risk Factors section, macroeconomic factors and events also have the potential to cause or contribute to significant delays in commencement and completion of our clinical trials. Global supply chain disruptions and the subsequent effects thereof may adversely affect the ability of contract manufacturers to manufacture and supply our clinical trial material. Our prospective or contracted clinical trial sites may experience resource constraints, including staffing shortages, stemming from global or regional issues, such as a pandemic or other public health emergency, 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 ongoing clinical trials, macroeconomic factors or events, such as a global pandemic, may result in lower than anticipated subject enrollment and completion rates, including because clinical trial sites may temporarily close or reallocate resources away from clinical research, or study participants may withdraw prior to receiving study treatment or discontinue their treatment or follow up visits to avoid medical settings or because they become sick or must care for a sick family member.

Significant clinical trial delays could have a material adverse impact on our financial condition and results of operations by substantially increasing the costs of our development programs. 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 complete development of or 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.

***Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products.***

The manufacture of our product candidates is complex and subject to compliance with extensive regulatory requirements, and in most cases we rely on single source contract manufacturers and suppliers. As a result, we face significant risks of manufacturing and supply delays and disruptions that may be difficult and expensive to resolve and may cause substantial delays in the development and regulatory approval of our product candidates or the commercialization of any approved product. To date, our clinical-stage product candidates have been tested in a relatively small number of clinical study participants. Significant scale-up of manufacturing will be required to provide adequate supplies of our product candidates for larger Phase 2 and Phase 3 clinical trials and may take longer and be more expensive than anticipated, potentially having a significant negative impact on our development costs and timelines. We have, and we expect we will continue to, face multiple challenges as our contract manufacturers scale their processes to provide supplies for larger clinical trials or commercial production including, among others, potential difficulties with process scale-up, process reproducibility, stability and purity issues, compliance with cGMP, lot consistency, and timely availability of acceptable raw materials.

For example, the ongoing pivotal clinical study of Ovaprene will require far more clinical product supplies than were manufactured for prior clinical and nonclinical studies combined. A substantial scale up in production was necessary to meet the study's requirements and required more time and expense than anticipated. Additional clinical supplies must be produced to complete the study and manufacturing disruptions may occur that extend the overall timeline and cost to complete the study. Under our agreement with ADVA-Tec, we are dependent on ADVA-Tec and its contract manufacturer, Poly-Med, Inc., for all Ovaprene clinical and commercial product supplies, and we do not control these third parties and have limited influence the efforts and resources they expend to meet our supply requirements. Furthermore, some of the key raw materials and components of Ovaprene have only a single source of supply. Global supply chain disruptions may also result in delays in and increased costs for the manufacture and supply of sufficient quantities of Ovaprene to meet the pivotal clinical study's requirements.

The manufacture of our product candidates is subject to extensive regulation. The finished products (and their APIs) used in clinical trials or approved for commercial sale must be manufactured in accordance with cGMP requirements in the U.S. that are enforced by the FDA and must comply with applicable requirements of foreign regulatory authorities for sales outside of the U.S. These regulations govern manufacturing processes and procedures, including record keeping and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of a product that may result in closure of the manufacturing facility for an extended period of time to investigate and remedy the contamination or inadvertent change. In addition, deviations anywhere in the manufacturing process could cause our product candidates to perform differently and affect the results of clinical trials. Further, even minor deviations in the manufacturing process, including filling labeling, packaging, storage and shipping, and quality control and testing, may result in shipment delays, lot failures, recalls or spoilage, and delay or disrupt our clinical studies or commercial supply of any approved product. If our contract manufacturers are unable to produce sufficient quantities of our product candidates (or their APIs) for clinical trials or, if approved, for commercialization at acceptable quality levels, our development and commercialization efforts would be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

As product candidates progress through the development process, it is not uncommon that manufacturing methods are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs, achieve consistent quality and results, or to comply with regulatory authority requirements. Any such changes carry risk that they will not achieve the intended objectives. If and when changes are made to the manufacturing process of our product candidates (or their APIs), we may be required by the FDA or foreign regulatory authorities to conduct bridging clinical or nonclinical studies or repeat one or more clinical trials to demonstrate comparable identity, strength, quality and purity of the product candidate before and after such changes, which could significantly increase development costs and delay regulatory approval or disrupt commercial supply. These manufacturing and supply risks are similarly applicable to any product or product candidate we license to a commercial collaborator and could adversely impact the timing or amount of potential milestone and royalty payments to us.

In addition, our cost of goods for our product candidates is at an early stage of development. The cost to manufacture our product candidates at commercial scale is difficult to predict currently. We may need to alter the materials, equipment or processes for making our product candidates in order to yield commercially viable products. As discussed above, manufacturing changes could increase development costs and timing and may not achieve the

intended objectives. Manufacturing costs may negatively impact the commercial viability of our product candidates, if approved.

See also “Risks Related to Our Dependence on Third Parties- We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third-party suppliers and manufacturers for clinical study materials, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, do not maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business,” and “- In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties and the risk of manufacturing disruptions” below.

***Many of our product candidates, including Ovaprene, will or may be considered combination products by the FDA and other regulatory authorities, which could increase the complexity, cost and timeline for their development and regulatory approvals. A change in the FDA’s prior determination that CDRH would lead the review of a marketing application for Ovaprene would adversely impact Ovaprene’s development timeline and significantly raise our costs to complete clinical development and obtain regulatory approval for Ovaprene.***

To the extent our product candidates meet the FDA's or any other regulatory authority’s definition of a combination product, the regulatory approval requirements can be more complex and costly because in addition to the individual regulatory requirements for each component, e.g., a drug and a medical device, additional combination product regulatory requirements may apply. The cost and timeline for development of product candidates determined to be combination products may be substantially greater than product candidates that are not considered combination products. See also ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Combination Products,” above.

Ovaprene is composed of both device and drug components and is considered a combination product by the FDA. The process for obtaining FDA approval of Ovaprene will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary. Ovaprene previously underwent a request for designation, or RFD, process with the FDA that determined that CDRH would lead the review of a PMA for potential marketing approval of this product candidate. If the designation were to be changed to CDER, or if either center 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. Based on discussions with the FDA, we believe that if our ongoing pivotal clinical study of Ovaprene 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, the impact of either a change in the lead FDA review center or the imposition of additional, currently unplanned requirements for approval could be significant to us and have a material adverse effect on the prospects for developing Ovaprene, as well as on our business and our financial condition. See also “The commercial success of Ovaprene will depend on market acceptance of a hormone-free monthly, intravaginal product, availability and effectiveness 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 disorders, including FSAD, are complex and there is limited clinical trial precedent from which to draw experience, making the design and execution of a clinical trial that demonstrates effectiveness of Sildenafil Cream in treating FSAD more inherently challenging and uncertain compared with investigational products for many other conditions.***

There are currently no FDA-approved pharmacologic treatments for female sexual arousal disorder, or FSAD, and there is no precedent program to reference in the design of our clinical trials for Sildenafil Cream. 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, and the product candidates' attributes, clinical studies to evaluate effectiveness in any subset of the conditions under the umbrella of Sexual Dysfunction, such as FSAD, are complex. While we worked with experts to develop novel patient reported outcome (PRO) instruments for our exploratory Phase 2b RESPOND study of Sildenafil Cream, tested the potential 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 RESPOND study proved more difficult to enroll than anticipated given the enrollment criteria for the study, particularly the requirement that the partner be enrolled in the study. Moreover, the Phase 2b

RESPOND study did not demonstrate statistical significance for the co-primary or secondary efficacy endpoints, although we determined that topline data supported continued clinical development of Sildenafil Cream and further analysis of the study data identified certain subsets of participants that achieved clinically meaningful and statistically significant improvement in certain items relating to the co-primary efficacy endpoints and data from the RESPOND study enabled successful completion of an end-of-Phase 2 meeting with the FDA and ongoing feedback from the FDA to align on key elements of the Phase 3 program for Sildenafil Cream.

Sildenafil Cream is designed to work primarily by increasing blood flow to the genital tissue. Therefore, identifying and enrolling patients in our clinical trials of Sildenafil Cream for whom inadequate blood flow to the genital tissue is the primary contributor to their arousal disorder is critical. 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. Conversely, trying to screen out patients with different contributing factors may slow enrollment in a study, delay its completion and increase its costs. In our exploratory Phase 2b RESPOND study, we experienced a slower than anticipated pace of enrollment given the enrollment criteria for the study, which lengthened our original estimated timeline for the study. We may experience delays in future clinical studies of Sildenafil Cream relative to our communicated expectations due to the novel nature of the studies and the complexities of the condition it is intended to treat, which may significantly lengthen clinical study timelines, increase overall costs, and may lead to unfavorable results.

With respect to any clinical study of Sildenafil Cream, even if we can identify and enroll a sufficient number of women for whom inadequate blood flow to the genital tissue is the primary contributing factor to their arousal disorder, there is no guaranty that the use of Sildenafil Cream will improve their general feelings of arousal or that the PRO instruments we utilize to measure the effectiveness of Sildenafil Cream in the study will adequately capture their genital arousal response. We expect to conduct two Phase 3 studies to support an NDA for Sildenafil Cream. Given the multiple factors contributing to arousal disorders and the novelty of the clinical endpoints that may be utilized to measure effectiveness of Sildenafil Cream in treating FSAD, we may be required to conduct multiple clinical trials in large patient populations, extending the timeline and increasing the cost of development for Sildenafil Cream, without any guarantee of positive results. If we are unable to efficiently and successfully advance Sildenafil Cream through clinical development, our business, operating results and financial conditional, as well as our stock price, could suffer.

***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 are 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 of clinical trials we report may differ from final results reported for those 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, complete 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 interim 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 than we do, 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 an extensive set of data and analyses, and investors and others may disagree with the information we determine is the material or otherwise appropriate information to include in our public disclosure. Information we determine not to publicly disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate, product 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 regulatory approval to market our product candidates in a timely manner, in particular, FDA approval. The regulatory approval processes of the FDA and comparable foreign authorities are expensive, lengthy, time-consuming, and inherently unpredictable. If we are not able to obtain regulatory approvals for our product candidates, our ability to generate product revenue will be materially impaired.***

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. Even if we successfully complete nonclinical studies, clinical studies, manufacturing and other required activities, we may still experience delays in our efforts to obtain marketing approvals for any of our product candidates. Marketing approval applications require the submission of extensive clinical and nonclinical data and supporting information to establish the safety and efficacy of our product candidates for the specified indication. The process of responding to the FDA or other regulatory authorities' information requests in the review process, potentially preparing for and appearing at a public advisory committee or oral hearing, and preparing our third-party manufacturers and clinical investigators to successfully complete inspections by the FDA or other regulatory authorities during the approval process requires significant human and financial resources.

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, updated interpretations of applicable policies, statutes or regulations, or upon review of outcomes of other similar product candidates under development. This could significantly lengthen our development timelines and cost.

The FDA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional clinical or nonclinical studies or changes in the manufacturing process or facilities, even if we had previously aligned with the relevant regulatory authorities on such data and other requirements. We cannot assure you that we will obtain any additional marketing approvals for our product or product candidates in any jurisdiction.

The announcement of new requirements by the FDA, the failure of a competitive product to receive regulatory approval, or the receipt of a complete response letter from the FDA by another company pursuing the FDA's 505(b)(2) pathway for product candidates identical to or similar to ours, any of which may have implications for our proposed regulatory authorization pathways, could impact how investors and potential strategic collaborators view the development risks associated with our product candidates. Changing testing or manufacturing requirements for our product candidates or for product candidates deemed to be comparable to ours may adversely impact our financial resources, our development timelines and may harm the perception held by others of our business.

***We expect to utilize the FDA's Section 505(b)(2) pathway for most of our current product candidates and if that pathway is not available, the development of our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complexity and risk than currently anticipated, and, in any case, may not be successful.***

We intend to develop and seek approval for many of our product candidates, including Sildenafil Cream, pursuant to the FDA's 505(b)(2) pathway. If the FDA determines that we may not use this regulatory pathway, then we would need to seek regulatory approval via a "full" or "stand-alone" NDA under Section 505(b)(1) of the FDCA. This would require us to conduct additional clinical trials and nonclinical testing, provide additional safety and efficacy data and other information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval, as well as the development complexity and risk associated with these programs, would likely substantially increase, which could have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. 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 our development programs relative to seeking approval under the 505(b)(1) regulatory pathway.

If the FDA changes its 505(b)(2) policies and practices or if Congress were to amend the statute to alter the currently available regulatory pathway, it 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 may have a material adverse impact on 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.

***Our clinical-stage 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 our clinical-stage product candidates, including Ovaprene and Sildenafil Cream, 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.

***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 collaborators, 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. Our portfolio includes several pre-clinical stage programs and if they fail to be adequately valued by investors or potential strategic collaborators, our business, financial condition and stock price may be adversely affected.

***Several 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.

***The grants supporting the DARE-LARC1 and DARE-LBT programs do not guarantee that pre-clinical development will be successful or that we will be able to fund their clinical development in the future.***

The grants supporting pre-clinical development of DARE-LARC1 and DARE-LBT, including the grant agreement under which we were awarded up to $48.95 million in non-dilutive funding for pre-clinical development of DARE-LARC1, do not guarantee that pre-clinical development will be successful, or, even if we are successful with all

specified pre-clinical activities, that we will be able to fund their future clinical development. Further, while we received aggregate payments of approximately $28.4 million under the 2021 DARE-LARC1 grant agreement as of December 31, 2023, additional payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones during the grant period and our compliance with other obligations under the agreement, and there is no assurance those milestones will be achieved or that we will receive additional payments or the full potential amount of the grant.

**Risks Related to Our Dependence on Third Parties**

***Our existing product development and commercialization collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, if these collaborations are not successful, or if we are unable to establish additional strategic collaborations, our business and prospects may be materially harmed.***

We have limited resources and no internal sales, marketing or distribution capabilities. A key aspect of our strategy is to establish collaborations with third parties, such as large and mid-size pharmaceutical companies and other third parties with the relevant R&D and/or commercial expertise and infrastructure to help bring our product candidates to market. We currently do not expect to directly market, sell or distribute any of our products that receive regulatory approval, and instead intend to enter into agreements with third parties to market, sell and distribute and provide related support services for those products. For example, we have entered into out-license agreements with third parties for the commercialization of XACIATO and, if approved, Ovaprene. We also have a CRADA for the conduct of a pivotal clinical study of Ovaprene with NICHD. We intend to seek additional strategic collaborations. However, these collaborations make the successful development and commercialization of our products and product candidates dependent upon the performance of third parties. By entering into strategic collaborations, we may relinquish control over important elements of product development and commercialization, and the collaborator may fail to develop or effectively commercialize the applicable products or product candidates. In addition, in the case of commercial collaborations, our product revenues, may be lower than if we were to sell and distribute products that we develop ourselves.

Our existing collaborations, and any future strategic collaborations we establish, involve significant risks to the success of the product, including that:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development or commercialization of a product or product candidate or elect not to continue or renew a collaboration based on clinical or nonclinical study results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, a public health emergency, or macroeconomic events or conditions, that cause them to divert resources to other initiatives or create competing priorities;
- collaborators may refuse to perform clinical studies or other development work required for approval in a particular jurisdiction outside the U.S.;
- collaborators may delay or stop clinical studies, provide insufficient funding for or abandon a clinical program, repeat or conduct new clinical studies or require a new formulation of a product or product candidate for clinical testing;
- collaborators could independently, or together with third parties, develop and commercialize products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more of our products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or product development or commercialization strategy, might cause delays or termination of the research, development or commercialization of our products or product candidates, might lead to additional responsibilities for us with respect to products or product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may violate, or be investigated for potentially violating, health care compliance and related laws and regulations, which may expose us to litigation, enforcement actions or inquiries, or other potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, could significantly delay product development and commercial launch and increase the cost to us to pursue further development or commercialization of the applicable product or product candidate. For example, our out-license agreements for XACIATO and Ovaprene and the CRADA with NICHD may be terminated by the counterparty for convenience upon the completion of a specified notice period, subject to limited restrictions.

If a collaborator terminates its agreement with us or if a collaboration does not result in the successful development of any product candidates and/or commercialization of any approved products, we may not receive any future royalty revenue, commercial milestones or other revenues under the collaboration, our development programs may not be funded as we expect, and our ability to establish another collaboration for the applicable product or product candidate may be negatively impacted. We may be unable to replace any commercial collaborator with an alternate third party on a timely or commercially reasonable basis, or at all. See also, “Risks Related to Our Financial Position and Capital Needs- If one of our commercial collaborators terminates its exclusive license agreement with us or fails to perform as expected, our need for additional capital may significantly increase,” above and “We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our product 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 development timelines and/or failure of our programs,” below. Moreover, the risks relating to product development, regulatory approval and commercialization and compliance with health care related laws and regulations described in this report also apply to the activities of our collaborators.

Except to the extent of any license fees or milestone payments under our current and any future collaboration agreements, because we currently have only one FDA-approved product, our ability to generate revenue over the next several years will largely be dependent on royalties and net sales-based milestones under our exclusive license agreement with Organon. Accordingly, our revenues may be dependent on Organon's ability to successfully market, sell and distribute XACIATO and to perform its contractual obligations. There is no assurance that commercialization of XACIATO in the U.S. will be successful, or that Organon will pursue development and commercialization of XACIATO outside of the U.S. The amount of royalty and milestone payments we will receive under the license agreement is uncertain. Apart from Organon's diligence obligation under our license agreement, we have no control over the efforts and resources Organon devotes to the marketing and sale of XACIATO. The occurrence of any of the risks described above could negatively impact the commercial success of XACIATO and have a material adverse effect on our business, financial condition and results of operations.

Termination of the CRADA by NICHD or by us could significantly delay the conduct and/or completion of the Phase 3 study of Ovaprene and significantly increase the overall timeline and costs for development of Ovaprene. Though the CRADA has a five-year term, either party may terminate it for any reason or for no reason upon 30 days’ prior written notice to the other party. If the CRADA is terminated before completion of the Phase 3 study of Ovaprene, NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study. If we terminate the CRADA before the completion of any active study protocol, we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the study. NICHD may retain and use the cash payments we have made under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination. If we fail to make any scheduled payment to NICHD under the CRADA, NICHD is not obligated to carry out R&D activities until it receives the funds. We have paid NICHD $5.0 million under the CRADA to date. Under the terms of the CRADA, a final payment of $0.5 million was due in the second quarter of 2023. Pursuant to our discussions with NICHD, we expect to make the final payment in the third quarter of 2024. Suspension by NICHD of activities under the CRADA or termination by NICHD or by us of the CRADA could have a material adverse effect on the Phase 3 study of Ovaprene and on our business, results of operations and financial condition, and may cause the market price of our common stock to decline.

We face significant competition in seeking strategic collaborations. Collaborations can also be complex and time-consuming arrangements to negotiate and document. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product or

product candidate, reduce or delay one or more of our other development programs, delay or reduce the scope of any commercial readiness activities, delay commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. 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 and other potential sources of market exclusivity for such product, the market performance of other products we developed, and industry and market conditions generally. The prospective collaborator may also have opportunities to collaborate with third parties on products or technologies that would compete with our products or product candidates and will evaluate whether those opportunities are more attractive than a collaboration with us. We 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.

We may also be restricted under existing collaboration agreements from entering into other collaborations on certain terms with other potential collaborators. For example, the terms of our exclusive license agreement also provide Organon exclusive worldwide rights of first negotiation for specified potential future products of ours, which may increase the complexity and time required, or otherwise inhibit our ability to transfer, license, sublicense, assign, grant or otherwise dispose of any rights in those potential future products to a third party, and lead to delays in their development and commercialization.

If we are not successful in attracting collaborators, entering into collaborations on acceptable terms and maintaining our collaborations for the products we develop, we may not complete development of or obtain regulatory approval for such products and product candidates, or if we obtain regulatory approval, commercial launch may be delayed and market penetration could be limited. 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.

***We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third-party suppliers and manufacturers for our clinical study supplies, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, fail to maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business.***

We do not own or operate, and we currently have no plans to establish, facilities for manufacturing, storage and distribution, or testing of product candidates. We rely and expect to continue to 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, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials, and conducting stability testing. In addition, we expect to continue to rely on third parties for commercial production and supplies of any future products. This reliance on third-party manufacturers and suppliers subjects us to inherent uncertainties related to product safety, availability, quality and cost.

Our product candidates (including their component materials) must be manufactured, packaged, tested, and labeled in accordance with our specifications and in conformity with cGMP and other applicable regulatory requirements, which requires dedication of substantial resources to specialized personnel, facilities and equipment and sophisticated quality assurance, quality control, recordkeeping procedures. While our employees and consultants monitor and audit our CMOs' manufacturing processes and systems, we have limited control over our CMOs and they may fail to perform as expected. The facilities and quality systems of CMOs who produce our product candidates and their APIs must pass a pre-approval inspection for compliance with applicable regulations as a condition of FDA approval. Failure to pass inspections, or to timely remediate any compliance issues identified by the FDA, could substantially delay marketing approval. As long as we are the product candidate sponsor or the holder of the product approval or manufacturer of record with the FDA or other regulatory authority, we are ultimately responsible for compliance with regulatory requirements for manufacturing and distribution of our product candidates and any future approved products, regardless of our lack of control over our third-party manufacturers and suppliers. Failure of those third parties to comply with cGMP and other applicable regulatory requirements may result in fines and civil penalties on us, suspension of production, delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval.

Our CMOs and component suppliers may experience delays in producing and supplying, or may become unable or unwilling to produce and supply, our clinical trial material or commercial supply material due to financial or personnel constraints, their obligations to, or their decision to prioritize the production and supply of products for, other customers, partial or full loss of their facilities, or supply chain disruptions, including as a result of geopolitical conflicts, macroeconomic events or conditions, natural or man-made disasters, or public health emergencies such as the COVID-19 pandemic. For example, our single source CMO for Ovaprene is located in an area of the U.S. that is vulnerable to tropical storms, hurricanes, flooding and tornadoes, which have potential to render its facilities inoperative for protracted periods. One or more of our CMOs may fail or be unable to perform at a time that is costly or inconvenient for us. We may not have adequate or any recourse against a CMO or supplier who does not perform or terminates its agreement with us if such non-performance or termination is excused under the applicable agreement. We do not have long-term supply agreements with any of our CMOs. We generally enter into manufacturing agreements on a project-by-project basis based on our development needs, which may heighten the risk of timely availability of sufficient quantities of our product candidates at acceptable costs for clinical trials. As we advance development of our product candidates, we will need to negotiate agreements for commercial supply and we may not be able to reach agreement on a timely basis or acceptable terms, or at all. In addition, the FDA or regulatory authorities outside of the U.S. may require that we have an alternate manufacturer of a product before approving it for marketing and sale in the U.S. or other jurisdiction, and securing such alternate manufacturer before approval of a marketing application could result in considerable additional time and cost prior to product approval.

Currently, we do not have alternative CMOs or API suppliers to back up our primary vendors of clinical trial material. Identification of and discussions with other vendors may be protracted and/or unsuccessful, or new vendors may not be successful in producing the same results as our current vendors on a timely basis at the appropriate volumes, at an acceptable cost, or at all. Therefore, if the current vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material or any future approved product for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results, and financial condition.

Any new CMO or API supplier would be required to qualify under applicable regulatory requirements. In some cases, the technical skills or technology required to manufacture our clinical trial material or commercial material may be unique or proprietary to the original CMO or supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such CMOs and suppliers or require us to obtain a license from them in order to have another third party manufacture our product candidates or any future approved product. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. In some cases, the FDA or a foreign regulatory authority may require us to conduct additional clinical or nonclinical studies, collect additional stability data, and provide additional information concerning any new CMO or supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. The process of identifying, verifying and transitioning to a new CMO or supplier could significantly delay development or regulatory approval of our product candidates or delay or disrupt commercialization of any approved product and substantially increase costs or result in significant loss of product sales and associated revenue.

If our CMOs encounter difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements, we may have insufficient quantities of material to support ongoing or planned clinical trials or to meet commercial demand for any approved product in the future. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical trials, increase the costs associated with our development programs, and depending upon the period of delay, require us to terminate the clinical trials completely and commence new clinical trials at significant additional expense. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. Manufacturing or quality control problems may arise in connection with the manufacture of our clinical trial material or future approved product and CMOs may not be able to maintain the necessary governmental licenses and approvals to continue their manufacturing services for us. In addition, with respect to any finished product or key components manufactured outside the U.S., such as the API for Sildenafil Cream, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, changes in currency fluctuations, shipping costs, or import tariffs could adversely affect cost of goods sold. Any of the above factors could cause us to delay or suspend anticipated or ongoing clinical trials, regulatory submissions or commercialization of a product candidate, entail higher costs, or result in being unable to effectively commercialize an approved product. Our dependence on third parties for the manufacture of our product candidates or future approved products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Similarly, while Organon now holds the FDA marketing approval and we have transferred XACIATO manufacturing responsibilities to Organon, commercial production and supply of XACIATO remains subject to comparable manufacturing risks as described herein, and any interruption in the commercial supply of XACIATO that directly or indirectly results in significant loss of product sales could have a material adverse effect on the payments we receive under our license agreement.

***In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties and the risk of manufacturing disruptions.***

Our agreement with ADVA-Tec restricts our ability to engage a manufacturing source for Ovaprene other than ADVA-Tec during Ovaprene's development period as well as following regulatory approval, subject to limited exceptions. If ADVA-Tec fails to provide sufficient clinical supply of Ovaprene on anticipated timelines, our ability to complete clinical development and seek regulatory approval of Ovaprene could be significantly delayed. A substantial scale up in production of Ovaprene clinical supplies was necessary to support the ongoing Phase 3 clinical study of Ovaprene, which took longer and was more expensive than anticipated, and if Ovaprene receives marketing approval, further substantial manufacturing scale up will be necessary. If Ovaprene receives marketing approval, failure by ADVA-Tec to provide sufficient commercial product quantities at reasonable costs could have a significant adverse effect on our revenue and ability to become profitable. Furthermore, for some key raw materials and components of Ovaprene, there currently is 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 was responsible for obtaining supplies of Sildenafil Cream for Phase 2 clinical trials conducted in the U.S., and we are responsible for providing supplies of Sildenafil Cream for Phase 3 clinical development and, if approved, for marketing and sale. We do not have any long-term manufacturing or supply agreements with the CMO from which we plan to obtain Sildenafil Cream for our first Phase 3 clinical study of Sildenafil Cream or with any supplier of the raw materials required to produce Sildenafil Cream. Future supplies of Sildenafil Cream or the raw materials required to produce Sildenafil Cream may be more difficult and costly to obtain. For example, the current supplier of sildenafil is located in India. Should this supplier slow production, shut down its factory or increase its prices for any reason, including due to factors outside of its control such as a public health emergency or geopolitical conflicts or events, we may not be able to obtain adequate supplies of sildenafil to satisfy our clinical supply requirements.

***We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our product 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 development timelines and/or failure of our programs.***

Our business model relies on the outsourcing of important product development functions, tests and services to CROs, medical institutions and other specialist providers, vendors and consultants. We rely on these third parties to conduct our clinical trials and perform related activities, including quality assurance, clinical monitoring and clinical data management, as well as to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals for our product candidates. For example, we engaged CROs to run all aspects of the pivotal Phase 3 clinical trial of XACIATO, the exploratory Phase 2b RESPOND clinical trial of Sildenafil Cream, the PCT clinical trial for Ovaprene, and our respective Phase 1/2 clinical studies of DARE-HRT1 and DARE-VVA1. In addition, our ongoing pivotal Phase 3 clinical trial of Ovaprene is being conducted by third parties under our CRADA with NICHD. We similarly expect to rely on CROs and other third parties to perform all clinical and nonclinical testing and many other important development and regulatory affairs activities needed to support applications for regulatory approvals of all product candidates we develop. 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 clinical trial delays or suspensions, delays in submission of our marketing applications or failure of a regulatory authority to accept our applications for filing. There is no assurance that the third parties we or our strategic collaborators engage will be able to provide the functions, tests, activities or services as agreed upon, or provide them at the agreed upon price and timeline or to our requisite quality standards, including due to macroeconomic factors, geopolitical conflicts or events, natural or manmade disasters, public health emergencies or pandemics or poor workforce relations or human capital management. We rely on the efforts of these third parties and if they fail to perform as expected, we could suffer significant delays and additional costs in, and potentially failure of, 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 could have a material adverse effect on our business, financial condition, results of operations and prospects.

In particular, as a result of the CRADA, we are highly dependent on NICHD and the third parties it engages for the conduct and completion of our ongoing pivotal Phase 3 clinical trial of Ovaprene. Pursuant to the terms of the CRADA, the study is being conducted within NICHD's Contraceptive Clinical Trial Network, or the CCTN, with NICHD's selected CRO providing clinical coordination and data collection and management services for the study. NICHD is responsible for selecting participating clinical sites from the pool of CCTN sites and, together with its selected CRO, overseeing the clinical investigators in the conduct of the study, providing clinical site monitoring and quality assurance along with establishing the electronic data capture database for the study and performing data analysis, which are key factors to the successful completion of a clinical trial. We do not control these third parties and, accordingly, our control over the conduct and completion of the study is limited. If NICHD or the third parties it engages for the study prioritize other projects over the study or otherwise do not devote adequate time and resources to the study, or their performance is substandard, completion of the study may be delayed or suspended or the study may be unsuccessful, which could significantly harm our business, operating results and financial condition, as well as our relationship with Bayer, and cause the price of our common stock to decline.

***Our ability to develop and commercialize our product candidates depends upon maintaining rights granted to us under license agreements with third parties. The loss or impairment of our rights under our in-license agreements relating to XACIATO or our product candidates could have a material adverse effect on our business prospects, operations and viability.***

We have rights to develop and commercialize XACIATO and our product candidates under license agreements between us and third-party licensors. The loss or impairment of these rights, including as a result of our inability or other failure (or that of our licensors, in the case of sublicenses) to meet our obligations under any one of such license agreements, including, without limitation, our payment obligations, could have a substantial negative effect on our business and prospects.

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 XACIATO for the treatment of bacterial vaginosis, 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. In addition to customary termination rights, MilanaPharm may terminate our license with respect to a licensed product or process in a country 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-Strategic Agreements for Pipeline Development-Hammock/MilanaPharm Assignment and License Agreement," above.

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 six months of obtaining a pre-market approval from the FDA, (3) with respect to the license in any particular country, fail to commercialize Ovaprene in that particular country within three 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. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development-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 for all indications for women related to female sexual dysfunction and/or female reproductive health, including treatment of 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-Strategic Agreements for Pipeline Development-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-PTB1. 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-Strategic Agreements for Pipeline Development-Catalent JNP License Agreement," above.

If we do not meet our obligations under our license agreements in a timely manner, some of which require the expenditure or payment to the licensor of significant amounts of cash, or if we are unable to obtain an extension of deadlines for satisfying our obligations, we could lose our rights under these agreements. Moreover, because some of our rights to XACIATO and our product candidates are sublicensed to us, our license agreements may be terminated or we may otherwise lose rights to intellectual property underlying our product or product candidates in the event of termination or loss of rights by our licensors, which may be outside of our control. There is no assurance that we would be able to renew or renegotiate license agreements on acceptable terms, or at all, if our existing license agreements (or the underlying agreements in the case of sublicenses) are terminated. Furthermore, 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 could result in the loss of our ability, or that of our sublicensees, to develop, manufacture, market or sell XACIATO or the product candidate covered by the agreement, as well as our ability to grant rights to other third parties to collaborate with us in the development and commercialization of our product candidates, which could have a material adverse effect on our business prospects and operations.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize, or maintain third-party collaborations to commercialize, the affected product or product candidate.

We may seek to license the product and technology rights to additional product candidates in accordance with our business strategy, 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 those candidates would ever be advanced successfully through clinical development.

**Risks Related to Commercialization of XACIATO and Our Product Candidates**

***The commercial success of XACIATO is outside of our control and will depend on Organon's efforts and capabilities, as well as a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our business and prospects may suffer.***

If commercialization of XACIATO is not successful, or is perceived to be unsuccessful, our business, financial condition, results of operations and prospects may suffer, particularly because XACIATO is the first and only product for which we have received regulatory approval. XACIATO's commercial success will depend on many factors, including:

- the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product;
- timely and adequate commercial supply of the finished product and its components;
- perceived superiority of its cure rates compared to other available treatments;
- the extent to which the approved product labeling contains features or expected benefits that differentiate it from other available treatments;
- preferences by health care providers and women for a vaginally administered therapy;
- the prevalence and severity of any adverse side effects;
- patient satisfaction and willingness to use it again and refer it to others;
- price pressure given the high level of generic treatments and changes in health care laws and regulations, including the Inflation Reduction Act of 2022;
- adequate coverage, pricing and reimbursement from third-party payors;
- the willingness of patients, without third-party insurance coverage or adequate reimbursement, to pay for the product;
- the success or failure of other branded therapies;
- market exclusivity provided by our intellectual property rights or conferred by regulatory authorities; and
- approval of new entrants, including alternative, non-antibiotic treatment options.

There is no assurance that Organon's efforts with respect to XACIATO will be successful or that product sales will be able to generate revenue to us at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals. See also the risks and uncertainties described under "Risks Related to Our Dependence on Third Parties," above.

***We have no internal sales, marketing or distribution capabilities. If we are unable to establish those capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product sales revenue.***

We do not have a product marketing, sales or distribution infrastructure. In order to commercialize any of our product candidates if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. As we move our product candidates through development toward, and in some cases, through regulatory approval, we evaluate several options for each product candidate's commercialization strategy. These options include building our own sales force and other commercial infrastructure, entering into strategic marketing partnerships with third parties, including commercial sales organizations or other pharmaceutical or biotechnology companies, out-licensing the product to other pharmaceutical or biotechnology companies, and combinations of these strategies. We currently have no commercialization agreements with third parties other than our license agreements with Organon for XACIATO and Bayer for Ovaprene. We may not be able to maintain our existing commercial collaborations or establish and maintain other commercial collaborations on favorable terms, on a timely basis, or at all.

To generate revenue from our product candidates, if approved, we may need to establish a commercial infrastructure. There are significant risks involved with establishing our own commercial infrastructure. For example, recruiting and training a sales force is expensive and time-consuming and could delay product launch. If we recruit and train a sales force and the commercial launch of the product is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred significant commercialization expenses. This may be costly, and our investment would be lost if we could not retain or reposition our sales and marketing personnel. Both the launch and ongoing commercial support of our products would require significant capital, which may not be available to us

when needed or on acceptable terms or at all. All of these factors could strain our cash resources and require us to raise additional capital. In addition, there is no guarantee that our efforts to generate product revenue would be successful.

Factors that may hinder efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- the lack of complementary products our sales personnel could offer, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

The risks described above may also apply if our commercial collaborations do not involve an exclusive license of substantially all commercialization rights to a third party and we instead enter into co-promotion arrangements with a third party.

Failure to timely enter into or maintain a commercialization arrangement with a third party or establish our own commercialization capabilities could significantly delay commercial launch of our products or require us to reduce the scope of any sales and marketing activities, which could have a material adverse effect on our business, financial condition and results of operations.

***Our product candidates, if approved, and XACIATO will face intense competition and our business and operating results will suffer if we, or our commercial collaborators, fail to compete effectively.***

The biopharmaceutical industry is intensely competitive and characterized by rapid technological developments. Our competitors and potential competitors include large, well-established pharmaceutical and biotechnology companies, many of which have robust product portfolios and strong franchises in women's health. Many of our competitors or potential competitors, either alone or with strategic collaborators, have:

- much greater financial, research, technical and human resources than we have at every stage of the product development and commercialization life cycle;
- more extensive experience in designing and conducting clinical trials, nonclinical studies, obtaining regulatory approvals, and in manufacturing, marketing and selling prescription medical products; and
- approved products or product candidates in late stages of development for one or more of our target indications.

Competitive products may be equally safe and as effective as our products, but sold at a substantially lower price. Alternatively, competitive products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than our products.

Our product candidates, if approved, will compete with products that have already been accepted by the medical community and patients. If our product candidates fail to generate compelling clinical results or if patients and health care providers fail to adopt our products for their respective indications, their commercial potential could be adversely impacted or severely diminished. It is possible that the potential advantages of our product candidates do not materialize or that the approved prescribing information for our products does not describe expected features or benefits. We also expect to face competition from new products that enter the market over time. We are aware of products currently under development intended for the same indications as our product candidates. These competitive product candidates may prove safer, more tolerable, more effective, and less expensive, and may be introduced to market earlier, or produced, marketed and sold more effectively or on a more cost-effective basis, than our product candidates. The success of competitive products may render our product candidates noncompetitive or obsolete, even prior to completion of their development.

With respect to XACIATO, there are many FDA-approved products for treating bacterial vaginosis, and many are generic. XACIATO will compete with those products. Current therapies for the treatment of bacterial vaginosis primarily consist of oral and vaginal formulations of antibiotics delivered as a single dose or through multiple doses over consecutive days. If health care providers do not view the prescribing information for XACIATO as compelling compared with other products available for the treatment of bacterial vaginosis, or if competitive products have better insurance coverage or reimbursement levels than XACIATO, health care providers may opt to continue to prescribe existing treatments rather than recommend or prescribe XACIATO to their patients. In addition, women may prefer orally delivered options to vaginally administered XACIATO unless they view XACIATO as providing significantly

superior efficacy, safety and/or convenience. Failure of our commercial collaborator to generate significant net sales of XACIATO would negatively effect the payments we receive under our license agreement.

***The women's health market includes many generic products and growth in generics is expected to continue, which could make the successful introduction of our branded products difficult and expensive.***

The proportion of the U.S. market made up of generic products has been increasing. If this trend continues, it may be more difficult for us or a commercial collaborator to introduce a new branded medical product, if approved, at a price that will allow us to achieve acceptable levels of revenue and net income from product sales. Generic competition is particularly strong in contraception and hormone therapy, which are areas in which our product candidates, if approved, will compete. In order for our branded products to develop commercial markets and for third-party payors to cover these higher cost products, our products must demonstrate better patient compliance and clinical benefit in their clinical trials compared to other available products.

Additional marketing and educational efforts may be required to introduce a new branded prescription medical product in order to overcome the trend towards generics and gain access to reimbursement by payors. If we or a commercial collaborator cannot introduce a product at the desired price or gain reimbursement from payors for the product, or if patients opt for a lower cost generic product rather than pay out-of-pocket or a higher co-pay for our product, our revenues or royalties and other license fees, as applicable, will be limited.

***XACIATO and any of our future approved products may fail to achieve the degree of market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, which would negatively impact our business.***

XACIATO and any future products may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If XACIATO and any future products do not achieve an adequate level of market acceptance, they may not generate significant net product revenue or net sales or result in significant payments to us from our commercial collaborators, we may suffer reputational harm and we may never become profitable. The degree of market acceptance of XACIATO and any future products will depend on several factors, including:

- the timing of our receipt of any marketing approvals and the jurisdictions in which marketing approvals are obtained;
- the terms of any approvals, such as any restrictions on the use of our product together with other medications;
- the indications for which the product is approved;
- demonstrated evidence of efficacy and safety;
- the approval and availability of alternative treatments and products for the same indications as our product;
- the prevalence and severity of any adverse side effects associated with our product;
- convenience and ease of administration for patients compared to alternative treatments and products, or other potential advantages and disadvantages compared to the alternatives;
- adverse publicity about our product or favorable publicity about competing products;
- our ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try a new product and of physicians to prescribe a new product;
- the success of any physician education programs for our product;
- the availability and extent of third-party coverage and reimbursement for our product and amount of out-of-pocket cost to patients;
- the willingness of uninsured patients to pay for the product;
- the willingness of pharmacy chains to stock the product; and
- effectiveness of our or our collaborators' sales and marketing strategy and efforts.

If XACIATO or any future product does not achieve an adequate level of market acceptance, it could have a material and adverse effect on our business, financial condition, results of operation and prospects.

***The commercial success of Ovaprene, if approved, will depend on market acceptance of a hormone-free, monthly intravaginal product, availability and effectiveness of alternative contraceptive products and women's preferences, as well as the success of Bayer's marketing and sales efforts.***

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 86%-91% typical use efficacy. Clinical testing will also need to demonstrate that the product can be safely worn for multiple weeks.

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 stage 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;
- competition from new lower dose hormonal contraceptives with more favorable side effect profiles;
- new generic contraceptive options including a generic version of the hormone-containing intravaginal product NuvaRing®;
- the effects of changes in health care laws and regulations on third-party payor coverage (including the birth control coverage mandate) and reimbursement and out-of-pocket costs to patients; and
- the availability and extent of third-party coverage and reimbursement for our product, the amount of out-of-pocket cost to patients and the effects of any changes in health care laws and regulations, including the birth control mandate, on product pricing and coverage and out-of-pocket costs to patients.

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. Should Ovaprene fail to generate compelling clinical safety and efficacy data, the license grant under our agreement with Bayer may never become effective. Even if Bayer elects to make the license agreement effective, Bayer has significant discretion in determining the resources that it will allocate to commercialization of Ovaprene and Ovaprene's commercial success may be limited, in which case our business, financial condition, results of operations and prospects could suffer significantly.

***The commercial success of Sildenafil Cream, if approved, will depend on the availability of alternative products for female sexual dysfunction disorders, the age group for which our product is indicated 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 to be the first product to receive such approval, one or more competitive products may be approved before our product. Even if we achieve our goal of being first-to-market for FSAD, the costs associated with introducing a new product into the sexual dysfunctions market would likely be significant, and regardless of the amount spent, there is no guarantee that our new product will be broadly adopted. Women may be hesitant to use Sildenafil Cream 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, particularly if it is not covered by insurance.

In addition, FSAD is a condition that impacts women of many ages, including older and elderly populations. We have not yet thoroughly studied the topical or clinical pharmacology of Sildenafil Cream in different patient populations, and sildenafil, the active ingredient in our drug candidate, 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 than younger populations. Based on our end-of-Phase 2 meeting with the FDA, we expect our pivotal Phase 3 clinical trials of Sildenafil Cream will be conducted in a premenopausal population. Therefore, we expect initial FDA approval of Sildenafil Cream, if received, would be limited to premenopausal women. Should Sildenafil Cream not be studied in older or elderly women, or, if studied in those populations, should it show increased risk of adverse reactions, or signs thereof, in older or elderly women during clinical development, the potential market for Sildenafil Cream could be significantly limited, which could have a material adverse impact on the value of this program.

If we receive marketing approval in the future, our commercial success with Sildenafil Cream will depend, in large part, on the ability of the product candidate to demonstrate safety and effectiveness in treating FSAD in clinical trials, as well as our ability, or that of a commercial collaborator, to educate doctors and women about the need to diagnose and treat FSAD and the potential benefits of using of Sildenafil Cream, which may not prove successful. Sexual arousal can be influenced by many emotional and physiological factors. To be successful, our clinical trials of Sildenafil Cream must anticipate such factors. Sildenafil Cream is designed to increase local blood flow to the genital tissue. Even if Sildenafil Cream demonstrates success in increasing blood flow, the product candidate may not demonstrate a significant, or any, increase in arousal or improvement in the overall sexual experience in some women in our clinical trials. If we fail to generate compelling clinical results, we may not receive regulatory approval to market Sildenafil Cream, or, if approved, many physicians may not prescribe and/or many women diagnosed with sexual arousal disorder may opt not to try Sildenafil Cream. If we fail to produce strong clinical outcomes, our ability to build a commercial market for Sildenafil Cream will be materially adversely impacted.

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

Treatments to address the symptoms associated with menopause, including the vasomotor symptoms, also known as 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 is designed to offer a convenient vaginal ring that continuously delivers a combination of bio-identical estradiol and progesterone over 28 days. Until relatively 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-HRT1 will need to compete with many types of hormone therapy options in terms of convenience, safety and efficacy in managing symptoms of menopause.

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

- preference for a vaginal ring delivery of hormone 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;
- preference for an FDA-approved product by women and health care providers over treatments prepared in compounding pharmacies;
- 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 and extent of third-party payor coverage and reimbursement for DARE-HRT1 and out-of-pocket cost for patients.

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.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses for prescription medical products. If we or any commercial collaborator is found or alleged to have improperly promoted any of our products for off-label uses, we may become subject to significant liability, including fines, penalties or injunctions, and reputational harm.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription medical products. In particular, a product may not be promoted for uses that are not approved by the FDA (i.e., off-label uses), as reflected in the product’s approved or cleared labeling. Promotional labeling and advertising for any of our drug product candidates that receive marketing approval, must be submitted to FDA at the time of first use and the agency actively solicits reports from health care professionals about improper promotional claims or activities by the drug manufacturer or distributor. Medical device promotion and advertising are subject to similar off-label restrictions, although without the same requirement to submit promotional materials to FDA at the time of first

use. Both prescription drug and medical device promotional materials must present a fair balance between the product's effectiveness and the risks associated with its use, and must be truthful and not misleading.

If we or a commercial collaborator is alleged or found to have promoted a product for any off-label use, we may become subject to significant liability and reputational harm. The federal government has levied large civil and criminal fines against companies for alleged improper medical product promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Other enforcement authorities may also take action against a company for promoting an off-label use of a prescription medical product, which could result in penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. See also "Risks Related to Our Business Operations and Industry- 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" below.

If we or our commercial collaborators, as applicable, cannot successfully manage the product promotion to ensure compliance with these legal and regulatory requirements, we could become subject to significant liability, our reputation could be damaged, and adoption of our products could be considerably impaired.

***Unexpected safety, efficacy or quality concerns relating to XACIATO could develop, which could have significant negative consequences for us.***

XACIATO was approved by the FDA based on prior findings of safety or effectiveness of previously approved clindamycin products and on clinical data from the Phase 3 DARE-BVFREE clinical trial, in which 307 patients were randomized and treated once. In light of its commercial launch, XACIATO will be used by larger numbers of patients, and some patients may use multiple regimens over the course of a year. New data may emerge from market surveillance or future clinical trials of XACIATO that give rise to safety, efficacy or quality concerns and result in negative consequences, including:

- modification to the product's prescribing information, such as the addition of boxed or other warnings, contraindications, or limitations of use;
- restrictions on the promotion or marketing of the product;
- issuance of "Dear Doctor Letters" or similar communications to health care professionals or the public regarding safety or efficacy concerns;
- imposition of post-marketing clinical trial requirements or other post-marketing studies;
- product distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy, or REMS, which could include elements to assure safe use;
- warning or untitled letters;
- suspension or withdrawal of marketing approvals;
- suspension or termination of ongoing clinical trials, if any;
- refusal by regulators to approve pending marketing applications or supplements to approved applications that we submit;
- suspension of, or imposition of restrictions on, the operations of our commercial collaborator or any CMO producing commercial supplies of XACIATO, including costly new manufacturing requirements;
- costly and time-consuming corrective actions;
- voluntary or mandatory product recalls or withdrawals from the market;
- significant reputational harm; and
- product liability claims and lawsuits.

Furthermore, the discovery of significant problems with another intravaginally administered or clindamycin-containing product perceived as comparable to XACIATO, could have an adverse impact on commercialization of XACIATO, including as a result of occurrence of the events described above. For example, XACIATO has not been studied in pregnant or breastfeeding women. Should increased risk of miscarriage or other adverse effects on maternal or fetal outcomes or breastfed infants be observed in future data from market surveillance or clinical trials of XACIATO or other clindamycin products, XACIATO's commercial potential may be limited and we could become subject to product liability claims and lawsuits.

The occurrence of any of the circumstances described above could reduce XACIATO's market acceptance, inhibit or delay its commercialization within or outside of the U.S. and adversely affect sales of XACIATO, which could, in turn, have a significant negative impact on the payments we receive under our license agreement with our commercial collaborator for XACIATO, as well as our stock price.

***If we suffer negative publicity concerning the safety or efficacy of XACIATO or the product candidates we develop, our reputation could be harmed, product sales could be adversely affected or we may be forced to cease or curtail product development efforts.***

If concerns should arise about the actual or anticipated clinical outcomes regarding the safety of XACIATO or any of our product candidates, including as a result of safety concerns related to third-party products containing the same or similar active or excipient substances, such concerns could adversely affect the market's perception of XACIATO and our product candidates. Negative publicity could be time consuming and expensive to address and could adversely affect potential opportunities with strategic partners or collaborators, lead to a decline in product sales, and negatively impact investor sentiment toward a product or product candidate or our company as a whole, which could lead to a decline in the price of our common stock.

***We are and will remain subject to ongoing regulatory requirements even after obtaining regulatory approval for a product candidate.***

Even if any of the product candidates we develop are approved by the FDA or a comparable regulatory authority outside of the U.S., as long as we are the holder of the product approval or manufacturer of record with the FDA or other regulatory authority, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities.

In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in our NDA or PMA submissions to the FDA.

Any marketing approvals we receive for our product candidates in the future may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. In addition, we will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities (when products are approved in foreign markets). Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance.

If a regulatory agency discovers previously unknown problems with a product, such as problems with the facility where the product is manufactured, or it disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or on us or our commercial collaborator, including requiring withdrawal of the product from the market. If we or our commercial collaborators are unable to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would require us and/or our commercial collaborators to expend significant time and resources in response and could generate adverse publicity. Any inability to comply with ongoing regulatory requirements may significantly and adversely affect our ability, or that of our collaborators, to develop and commercialize our products and the value of our business, and our operating results would be adversely affected.

***Failure to successfully obtain coverage and reimbursement for XACIATO and any future products in the United States, or the availability of coverage only at limited levels, would diminish our ability, or that of a commercial collaborator, to generate net product revenue or net sales.***

Coverage from government health care programs and private commercial health insurance companies is critical to the commercial success of XACIATO and any future products. Market acceptance and sales of XACIATO and any future products that we or a commercial collaborator may seek to commercialize will depend in part on the extent to which reimbursement for these products will be available from third-party payors. Third-party payors, such as government health care programs, private health insurers, managed health care providers, and other organizations, are increasingly challenging medical product prices and examining the medical necessity and cost-effectiveness of medical products, in addition to their safety and efficacy. If these third-party payors do not consider XACIATO or any future product to be cost-effective compared to other available therapies and medical products, they may not cover the product as a benefit under their plans or, even if they do, the level of payment may not be sufficient to allow us, or a commercial collaborator, to sell the product on a profitable basis. Coverage decisions can depend upon clinical and economic standards that disfavor new prescription medical products when more established or lower cost alternatives are already available or subsequently become available. Third-party payor coverage may not be available to patients for XACIATO or any future product. If third-party payors 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.

Significant uncertainty exists as to the reimbursement status for newly approved prescription medical products, including coverage and payment. There is no uniform policy requirement for coverage and reimbursement for prescription medical products among third-party payors in the U.S.; therefore, coverage and reimbursement for our products could differ significantly from payor to payor. In the U.S., the principal decisions about reimbursement for new medical products are typically made by the Centers for Medicare and Medicaid Services, or CMS, as CMS decides whether and to what extent a new medical product will be covered and reimbursed under Medicare. Third-party payors often rely upon Medicare coverage policy and payment limitations to a substantial degree in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. It is difficult to predict what CMS will decide with respect to reimbursement. Decisions regarding the extent of coverage and amount of reimbursement to be provided for XACIATO and any future products will be made on a payor-by-payor basis. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Moreover, reimbursement agencies in Europe may be more conservative than CMS, should XACIATO or any of our product candidates be approved for marketing in Europe.

In addition to CMS and private payors, professional organizations can influence decisions about reimbursement for new medical products by determining standards of care. In addition, many private payors contract with commercial vendors who sell software that provides guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit as compared to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of any of our commercialized products.

To secure coverage and reimbursement for XACIATO and any future product, we or a commercial collaborator may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product to third-party payors, which costs would be in addition to those required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. 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. Third-party payors increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for XACIATO or any future product, or obtaining such pricing or placement at unfavorable pricing levels, could materially adversely affect our business, financial conditions, results of operations and prospects. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, or those of a commercial collaborator. Interim payments for new products, if applicable, also may not be sufficient to cover our costs, or those of a commercial collaborator, and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S.

Accordingly, the coverage determination process is often a time-consuming and costly process that will require us or our commercial collaborator 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 cost prohibitive for health care providers or their patients, or less profitable than alternative treatments or products, or if administrative burdens make our products less desirable to use. Our inability, or that of our commercial collaborator, to obtain coverage and profitable payment rates from both government-funded and private payors for XACIATO or any future product could have a material adverse effect on our operating results, our ability to raise capital needed to execute our business strategy and our overall financial condition.

Failure by us or a commercial collaborator to obtain timely and adequate coverage and pricing for XACIATO and any future products, or obtaining such coverage and pricing at unfavorable levels, could materially adversely affect our business, financial condition, results of operations and prospects.

***Legislation and legislative and regulatory proposals intended to contain health care costs may adversely affect our business.***

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 of 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 and prescription drugs. Individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

The Biden Administration has also indicated that lowering prescription drug prices is a priority, and on August 16, 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, the Centers for Medicare and Medicaid Services, or CMS, will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the U.S. remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing. Further, in December 2023, the Biden Administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"), and the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

It is uncertain whether and how future legislation or regulatory changes could affect prospects for XACIATO or our product candidates or what actions third-party payors 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, or the ability of a commercial collaborator, to commercialize any future products as well as our ability to generate revenue and attain profitability.

***Even seemingly small copayments or other cost-sharing requirements could dramatically reduce the market potential for XACIATO and our product candidates.***

If the out-of-pocket costs for XACIATO or any of our product candidates, if approved, are deemed by women to be unaffordable, or if less expensive alternatives exist, a commercial market may never develop or the market potential for that product may be significantly reduced, which could have a material adverse effect on our business, financial condition, and prospects.

With regard to contraceptive products, the ACA and subsequent regulations enacted by 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 in the U.S. 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 contraceptive products. In January and July of 2022, the DHHS, Department of Labor, and Treasury Department jointly issued guidance on implementation of this ACA mandate, among other things. The federal guidance makes clear that all FDA-approved or cleared contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without cost sharing, regardless of whether the product is specifically identified in a Birth Control Guide published by the FDA. Any future repeal or elimination of the ACA's 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 or branded prescription contraceptive products, including Ovaprene and our other investigational contraceptive products, if and when approved by the FDA.

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

Sildenafil Cream is being developed for female sexual arousal disorder, a life altering, but not a life threatening, condition. Hence, there is no assurance that third-party reimbursement will be available for Sildenafil Cream, if approved. 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 to be a lifestyle 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 FSAD treatments as well. The safety and efficacy data from our clinical trials may impact whether Sildenafil Cream 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 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, which would have a material adverse effect on our financial condition and prospects.

***The commercial success of products we develop, if approved, will be impacted by the prescribing information approved by the FDA and comparable regulatory authorities outside the U.S.***

The commercial success of any products we develop will significantly depend upon our ability, or that of our commercial collaborator, to obtain approval from the FDA and other regulatory authorities of prescribing information for the product that adequately describes expected features or benefits. Failure to achieve such approval will prevent or substantially limit our or our collaborators' ability to advertise and promote such features and benefits in order to differentiate our products from competing products. This failure could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Drug products and drug/device combination products are complex to manufacture, and manufacturing disruptions may occur that could cause significant delays and disruption in the commercial supply of any product we develop, if approved.***

The manufacture of our product candidates is complex, subject to compliance with extensive regulatory requirements and we are dependent on, and expect to continue to rely on, contract manufacturers and other third parties to supply our products and their components. Manufacturing disruptions may occur, including as a result of scaling up production to meet commercial requirements or due to global supply chain disruptions. Such problems may prevent the production of lots that meet the specifications required for sale of a product and may be difficult and expensive to resolve. To the extent we or our commercial collaborators rely on single source contract manufacturers and suppliers, if disruptions occur in the operations of any one of those third parties, there may be immediate shortages of our products. If any such issues were to arise, we could lose sales and associated revenue, incur additional costs, delay commercial launch of new products or suffer harm to our reputation.

See above: “Risks Related to Product Research & Development and Regulatory Approval- Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products.”; “Risks Related to Our Dependence on Third Parties- We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third-party suppliers and manufacturers for clinical study materials, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, do not maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business;” and “Risks Related to Our Dependence on Third Parties- In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties and the risk of manufacturing disruptions.”

***If competitors obtain approval for generic versions of XACIATO or any future products, our business may suffer.***

XACIATO and any future product may face direct competition from generic products earlier or more aggressively than anticipated, depending upon the product's success in the market. In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Act amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications, or ANDAs. An ANDA relies on the nonclinical and clinical testing conducted for a previously approved reference listed drug, or RLD, and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is “bioequivalent” to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If a third party is able to demonstrate bioequivalence without infringing our patents or if a data exclusivity period granted to a product under the FDCA is successfully challenged, a third party may be able to introduce a competing generic product onto the market before the expiration of the applicable patents or exclusivity period under the FDCA. Reduction or loss of periods of market exclusivity for our products could negatively affect our business, operating results and financial condition.

***We will need to obtain FDA approval of any proposed prescription medical product name, and any failure or delay associated with such approval may adversely affect our business.***

Any name we intend to use for our current or future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed new prescription medical product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a proposed product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose any goodwill or brand recognition developed for previously used names and marks, such as Ovaprene, as well as the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. We or a commercial collaborator may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our or our collaborator’s ability to commercialize our product candidates.

***Even if we receive marketing approval from the FDA, we may fail to receive similar approvals outside the U.S., which could substantially limit the value of our products.***

To market any future product outside the U.S., we, or our commercial collaborators, must obtain separate marketing approvals from comparable regulatory authorities for 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 U.S., as well as other risks. Further, for approval in foreign jurisdictions, we may not have rights to reference the necessary clinical and nonclinical data that we do not own or have licensed rights to use, as we anticipate doing under the 505(b)(2) regulatory pathway in the U.S., and we, or our commercial collaborator, may have to conduct further

nonclinical studies or clinical trials or develop other additional data to seek approvals in other jurisdictions. In addition, in many countries outside the U.S., 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 U.S. may be different and inconsistent with the U.S. labeling requirements, negatively affecting our ability to market our products in countries outside the U.S.

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, or our commercial collaborator, fail to comply with applicable foreign regulatory requirements. In such an event, our ability, or our commercial collaborator's ability, to market to the full target market for our products will be reduced and the full market potential of our products may not be realized, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Employee Matters and Managing Our Growth**

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

As of March 27, 2024, we had 26 employees, of which 24 were full-time and five were part-time. Our focus on limiting cash utilization requires us to manage and operate our business in a highly efficient manner, relying on consultants and other third-party service providers for product development and operational expertise we require, and to limit full-time personnel resources. With a small number of employees, our ability to supervise the service providers we engage, including our CMOs and CROs, 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.

We generally allow for a hybrid work model. We instituted remote work policies in March 2020 in response to the COVID-19 pandemic and resulting government stay-at-home orders, which have evolved into our current policies generally permitting a hybrid work schedule. In addition, many consultants, collaborators and other third-party service providers on which we rely currently have a remote or hybrid workforce model. The long-term impact of less frequent in-person meetings on our productivity and creativity is difficult to assess. Remote working arrangements for our personnel and that of third parties on which we rely may weaken our ability to effectively manage and operate our business and lead to delays in our anticipated development program timelines.

In addition, due to our small workforce, if multiple employees were to become unable to work for a protracted period for any reason, or if they were to resign at roughly the same time, our business could suffer. Our ability to effectively manage and operate our business could become significantly impaired and our expenses could increase materially, including as a result of expenditures related to recruiting, hiring and training qualified new employees and engaging additional consultants and service providers to perform the job responsibilities of the employees on leave or who resign. If we or our collaborators or service providers experience staffing shortages, it may result in significant 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 biopharmaceutical industry 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 our senior management, and our chief executive officer in particular, could impede, delay or prevent the development and commercialization of our product candidates, harm 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 team, 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 biopharmaceutical companies and other life sciences R&D organizations, 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. Many of the other companies 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 opportunities 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.

***We may not be successful in our efforts to identify and acquire or in-license additional product candidates or technologies, which may limit our growth potential.***

Our business development strategy involves identifying and acquiring or in-licensing potential product candidates or technologies. We assembled our current portfolio of product candidates through the acquisition of companies and assets and in-licensing transactions beginning in 2017. We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense.

These efforts may not be successful, including for reasons discussed in elsewhere in this Risk Factors section and also:

- we may fail to appropriately evaluate the potential risks and uncertainties associated with a transaction;
- there may be intense competition to acquire or in-license promising product candidates and technologies and many of our competitors have considerably more financial, development and commercialization resources than we have;
- we may not effectively integrate the acquired or in-licensed assets, businesses, personnel, intellectual property or business relationships;
- we may underestimate the development and regulatory approval challenges, costs and timelines and overestimate the market opportunity for the potential product candidates and technologies; and
- during development, the acquired or in-licensed product candidates may not prove to be safe or effective in their targeted indications.

We may fail to realize the anticipated value of any strategic transaction and the costs of a transaction may outweigh the benefits we realize from it. In addition, we have used shares of our common stock as consideration in strategic transactions and we may do so in the future, which may result in significant dilution to our stockholders. Any strategic transaction we pursue may not produce the outcomes and benefits we originally anticipated and may adversely impact our operating results and financial condition and be detrimental to our company in general.

**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 U.S. and other countries for the intellectual property covering or incorporated into our technologies and products. Many of 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.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent

application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We cannot be certain if any of the patents that cover our product candidates will be eligible to be listed in the Orange Book following a drug product marketing approval. 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 applicant (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. This could enable our competitors to develop a competing product that avoids infringing our patents. In such an event, our competitors might be able to enter the market, which could significantly harm the commercial opportunity for our product candidates.

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, products and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets.

As an example, the complexity and uncertainty of European laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which are subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Our patent strategy for protecting Ovaprene includes in-licensing several patent families from ADVA-Tec. 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 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 U.S. However, if granted 3-year exclusivity, generic applicants can still submit an abbreviated application during the 3-year period and the 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, 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 and DARE-FRT1, The General Hospital Corporation (also known as Massachusetts General Hospital or 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.

With respect to patents rights related to our DARE-GML program, the University of Minnesota (UMN) has the sole right to prosecute and maintain its patent rights, and we have the right to prosecute and maintain patents licensed from Hennepin Life Sciences. We will be responsible for the costs incurred by UMN 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 UMN's implementation of the patent strategy.

With respect to patent rights licensed from Douglas and underlying patent rights from University of Manchester, Douglas has the sole right to prosecute and maintain those patent rights. We will be responsible for the costs incurred by Douglas 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 Douglas's implementation of the patent strategy.

There is a substantial backlog of patent applications at the USPTO that may lead to delays in having patent applications examined by the USPTO. There can be no assurance that any patent applications relating to our products or methods will be issued as patents or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. We 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 enforcement 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 U.S. 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 U.S. 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 and XACIATO 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, is sildenafil and the active ingredient in our FDA-approved product for the treatment of bacterial vaginosis, XACIATO, 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, or any GAIN Act extension thereof, 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 and XACIATO 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 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 XACIATO, 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 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 XACIATO. Additionally, our license agreement with Organon requires that we indemnify Organon from and against all liabilities, damages, expenses, fines, penalties and losses as a result of any third-party claim arising out of or relating to the development, manufacture, commercialization or other exploitation of XACIATO or any licensed product by or on behalf of us or any affiliate or licensee of ours, except for in limited circumstances. As a result of our indemnification obligations to Organon and limitations on TriLogic's and MilanaPharm's obligations to indemnify us, any patent infringement litigation relating to XACIATO 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 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, 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.

With respect to our IVR product candidates, including DARE-HRT1, DARE-FRT1, and DARE-PTB1 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.

We cannot guarantee that we or any of our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S., Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the U.S., applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S., EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our or our licensors' interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We or our licensors may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our or our licensors' determination of the expiration date of any patent in the U.S., the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our licensors' failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

From time to time, we or our licensors may identify patents or applications in the same general area as our products and product candidates. We or our licensors may determine these third-party patents are irrelevant to our business based on various factors including our or our licensors' interpretation of the scope of the patent claims and our or our licensors' interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our or our licensors' determinations. Further, while we or our licensors may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us or our licensors. We cannot guarantee that we or our licensors will be able to successfully settle or otherwise resolve such infringement claims. If we or our licensors fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We or our licensors might, if possible, also be forced to redesign our product candidates so that we or our licensors no longer infringe on the third-party intellectual property rights. Any of these events, even if we or our licensors were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

***We also rely upon trade secrets to protect our technology, product and product candidates, and trade secrets can be difficult to maintain and enforce.***

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to derive a competitive advantage for products we develop, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to maintain. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, 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 party illegally disclosed or obtained and is using trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. 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.

Our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors may be able to legally obtain products of ours and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our know-how, trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

We enter into confidentiality and nondisclosure agreements with our employees, CROs, CMOs, consultants, collaborators, sponsored researchers, and scientific and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party on our behalf or made known to the party by us during the course of the party's relationship with us. We also enter into intellectual property assignment agreements with our employees, consultants and certain other service providers, which generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored or may not effectively assign intellectual property rights to us. We have not entered into any non-compete agreements with any of our employees. We cannot guarantee that the confidential nature of our proprietary information will be maintained by our employees and others in the course of their future employment with or provision of services to a competitor. Enforcing a claim that a party illegally disclosed or obtained and is using our know-how, trade secrets or other proprietary information is difficult, expensive and time consuming and the outcome is unpredictable. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage for the products we develop, which could materially adversely affect our business, operating results and financial condition.

***Provisions in our agreements with governmental agencies and non-profit organizations may affect our intellectual property rights and the value of our development programs to our company.***

Certain of our product development activities have been funded, are being funded and may in the future be funded, by the U.S. government and/or not-for-profit organizations. Our agreements for these sources of funding

include, and may in the future include, terms and conditions that affect our intellectual property rights. For example, under our CRADA with NICHD for the Phase 3 clinical study of Ovaprene, the U.S. government has a nonexclusive, nontransferable, irrevocable, paid-up right to practice for research or other government purposes any invention of either party conceived or first actually reduced to practice in the party's performance of the CRADA and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U.S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed.

The U.S. federal government retains certain rights in inventions produced with its financial assistance. Under the Bayh-Dole Act, the federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in" rights. March-in rights allow federal agencies, in specified circumstances, to require the recipient of federal funding (the contractor) or successors in title to the patent to grant a nonexclusive, partially exclusive or exclusive license to a third party if it determines that (i) adequate steps have not been taken to achieve practical application of the invention, (ii) government action is necessary to meet public health or safety needs, (iii) government action is necessary to meet requirements for public use under federal regulations or (iv) unless the requirement has been waived, the contractor has failed to substantially manufacture in the U.S. any product embodying the subject invention that is intended for U.S. commerce. If the contractor or its successor refuses to do so, the government may grant the license itself. The federal government also has the right to take title to these inventions if the contractor or its successor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. To date, no federal agency has ever exercised march-in rights; however, the Biden administration has announced that it views march-in rights as a legitimate means for the government to address rising pharmaceutical costs and future use of march-in rights by the government is uncertain. Any exercise by the government of march-in rights could harm our competitive position, business, financial condition, results of operations and prospects.

Under the grant agreements supporting development of DARE-LARC1 and DARE-LBT, we agreed to make DARE-LARC1, DARE-LBT and any other products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the respective projects funded by the respective grants (referred to as Funded Developments), available and accessible at an affordable price to people most in need within developing countries, and to promptly and broadly disseminate the knowledge and information gained from the project funded by the grant (referred to as the Global Access Commitment). In connection with the Global Access Commitment, under the agreement, we also granted the foundation that awarded the grant a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and essential background technology (referred to as the Humanitarian License). We are required to ensure that the Humanitarian License survives the assignment or transfer of Funded Developments and essential background technology. Our obligations under the Global Access Commitment and the Humanitarian License may limit the value to us of DARE-LARC1 and other Funded Developments.

**Risks Related to Our Business Operations and Industry**

***Business interruptions resulting from public health crises, natural disasters or telecommunication and electrical failures may materially and adversely affect our business, operating results and financial condition.***

We may experience significant business disruptions as a result of a public health emergency, natural or man made disaster, act of terrorism, war, or telecommunications or electrical failure that impacts our facilities or employees, or those of the third parties on which we rely for key business activities. The effects of such events or conditions may materially and adversely affect our product development activities in the future, including as a result of:

- difficulties and delays in clinical study site initiation, including due to diversion of healthcare resources away from conducting clinical studies;
- difficulties and delays in recruiting and enrolling clinical study participants and conducting follow-up visits;
- interruption of key clinical study activities, such as study site and data monitoring, due to limitations on travel or in-person gatherings;
- staff disruptions and turnover internally or at our CMOs, CROs, clinical study sites, collaborators or other third parties on which we rely, either directly or indirectly as a result of reallocation of resources, illness, vaccine mandates or other changes in terms of employment;
- delays in receiving approval from regulatory authorities or IRBs to initiate our clinical studies;

- difficulties and delays in production of clinical trial materials and commercial product, including due to supply chain disruptions or resource constraints or reallocation on the part of our CMOs and raw materials suppliers;
- interruptions in U.S. or global shipping that may affect the transport and delivery of raw materials, clinical study materials and commercial product;
- changes in local regulations in response to a public health emergency or other emergency situation that may require changes in the ways our clinical studies are conducted, require us to discontinue a clinical study, or make it more difficult for commercial and medical affairs field teams to call on or otherwise access healthcare providers;
- patient delays in seeking or receiving treatment, either due to fear of infection or inaccessibility of healthcare providers;
- delays in interactions with the FDA or a foreign regulatory authority necessary to advance clinical development of our product candidates, or delays in their review process and timing of potential approval of our product candidates, including delays in pre-approval manufacturing or clinical study site inspections;
- difficulties and delays in establishing or maintaining strategic commercial or development collaborations due to the reallocation of resources or shifting business strategies of collaborators or potential collaborators away from the women's health market in general or our areas of focus within women's health in particular; or
- disruption and volatility in the financial markets which negatively impacts our access to additional capital or stock price.

For example, in March 2020, the COVID-19 pandemic began to impact the global economy. Because of its size and breadth and the continued emergence of new variants, all of the direct and indirect consequences of the COVID-19 pandemic are not yet known and may not emerge for some time. The COVID-19 pandemic disrupted our product development activities and the business activities of third parties on which we rely. The COVID-19 pandemic contributed to a slower than anticipated pace of enrollment of participants in our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream as a result of operational restrictions or closure of certain study sites due to their adherence to governmental guidelines intended to reduce the spread of COVID-19. The COVID-19 pandemic also caused us to prioritize advancement of certain of our development programs over others, or certain development activities within a program over others, due to anticipated or actual difficulties and delays in recruiting clinical study sites and participants and obtaining clinical trial materials and supplies.

The strategies we implement designed to mitigate the effects or potential effects on our business of a public health emergency such as the COVID-19 pandemic, a natural or manmade disaster, act of terrorism, war or telecommunications or electrical failure that impacts our facilities or employees or those of third parties on which we rely may not be effective. The occurrence of such an event or condition could cause significant delays in the timelines for our clinical studies, our regulatory submissions or potential marketing approvals of our product candidates, substantially increase our development costs, and delay or contribute to delays in the commercial launch of any approved product or market acceptance of the product. The longer such an event or condition persists, the greater the potential for significant adverse impacts to our business operations and those of the CROs, CMOs, commercial collaborators, and other third-party service providers and vendors on which we depend to, among other things, conduct our clinical and nonclinical studies, supply our clinical trial materials, assist with regulatory affairs necessary to advance and seek regulatory approval for our programs, and market, sell and distribute our products, if approved.

Public health emergencies, natural or man made disasters, acts of terrorism, war or telecommunications or electrical failures may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

***Product liability lawsuits against us could cause us to incur substantial liabilities.***

We face an inherent risk of product liability exposure as a result of testing of our product candidates in human clinical trials and will face an even greater risk following commercial launch of a product we develop. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities or be required to limit commercialization of our products. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any marketed product;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- termination of product development or commercial collaborations;
- loss of revenue;
- withdrawal of clinical study participants and delays in commencement or completion of clinical studies;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients or clinical study participants;
- diversion of our management's time and other resources from pursuing our business strategy; and
- a decline in our stock price.

We carry product liability insurance that we believe to be adequate for our clinical testing and product development programs and in connection with XACIATO. However, insurance coverage is increasingly expensive, and it may be difficult to obtain adequate product liability insurance in the future. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of any of our product candidates, if approved. We also have indemnification obligations to our commercial and other collaborators. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

***Our current or future employees, clinical investigators, commercial collaborators or service providers may engage in misconduct or other improper activities, including non-compliance with regulatory standards.***

We may become exposed to the risk of employees, clinical investigators, commercial collaborators, CMOs, CROs, consultants or other vendors engaging in fraud or other misconduct. Misconduct by our employees or third parties on which we rely for the development and commercialization of our products and product candidates 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 clinical and nonclinical research standards and manufacturing standards established by us and/or required by the FDA or other laws and regulations, 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, clinical investigators, commercial collaborators, CROs, consultants or other 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 these parties, 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.

***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 providers and third-party payors play a primary role in the recommendation and prescription of drug products and medical devices that are granted marketing approval. Our arrangements with health care providers, commercial collaborators, principal investigators, consultants, third-party payors, customers and other organizations may expose us to broadly applicable fraud and abuse and other health care laws and regulations in the U.S. 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 operations include:

- the federal Anti-Kickback Statute (and comparable state laws), which prohibits, among other things, any person from knowingly and willfully offering, providing, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback

Statute to reach large settlements with health care companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- federal and state civil and criminal false claims laws, including the civil False Claims Act which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the U.S. Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;
- federal, civil and criminal statues created under HIPAA (and similar state laws), which prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the Physician Payments Sunshine Act, enacted as part of the ACA, which, among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report to CMS, on an annual basis, information related to payments and other transfers of value to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non-physician health care practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members in such manufacturers;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose specified requirements relating to the privacy, security and electronic exchange of individually identifiable health information, or "protected health information" when subject to HIPAA. Among other things, HITECH makes some of HIPAA's privacy and all of HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. "Covered entity" or entities that must comply with HIPAA, include certain health care providers, health plans, and health care clearinghouses. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and third parties unlawfully in possession of protected health information, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions; and
- the U.S. Foreign Corrupt Practices Act, which prohibits U.S. organizations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers of value to non-U.S. officials, which in many countries, could include interactions with certain health care professionals.

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.

The risk of violation of, and subsequent investigation and prosecution for violations of, the laws described above may be mitigated through the implementation and maintenance of compliance programs by us and our commercial collaborators and other third parties on which we rely for important aspects of development or commercialization of our products and product candidates, but these risks cannot be eliminated entirely. Ensuring that our current and future business operations and arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving

applicable fraud and abuse or other health care laws and regulations. If we or our operations, or those of a commercial collaborator or other third party on which we rely for development or commercialization of our products and product candidates, are found to be in violation of any of the laws described above or any other governmental regulations that apply to us or that third party, we may be subject to significant civil, criminal and administrative penalties, including monetary damages, fines, individual imprisonment, disgorgement, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, health care reimbursement or other government programs, including Medicare and Medicaid, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and/or the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

If regulatory authorities challenge our activities, or those of a commercial collaborator or other third party on which we rely, under these laws, any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any investigation of us or the third parties with whom we contract, including a commercial collaborator, regardless of the outcome, would be costly and time consuming, and may negatively affect our results of operations and financial condition.

***Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our collaborators or third-party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information, subject us to significant financial loss, and expose us to liability, any of which could adversely affect our business and our reputation.***

We utilize information technology systems and networks in the ordinary course of our business to process, transmit and store sensitive data, including confidential information, intellectual property, and personally identifiable information of our employees, consultants and others. As the use of digital technologies has increased, cyber incidents, including deliberate attacks (such as the deployment of harmful malware and other malicious code, ransomware, denial of service, social engineering, and other attempts to gain unauthorized access to computer systems and networks), have increased in frequency and sophistication, and have become increasingly difficult to detect. These threats pose a risk to the security of our systems and networks and those of our collaborators and third-party service providers, which store sensitive data of ours, and could compromise the confidentiality, availability and integrity of information stored there which is vital to our operations and business strategy. A successful cyber-attack could cause serious negative consequences for us, including, without limitation, the disruption of our operations, the misappropriation or destruction of our confidential information and sensitive data, including clinical trial data, corporate strategic plans and financial information, and the misappropriation of other assets, including our cash. Organizations and governmental bodies with far greater resources than ours dedicated to cybersecurity have proven vulnerable to cyber-attacks. There can be no assurance we will succeed in preventing cybersecurity breaches or successfully mitigate their effects. In March 2023, we became aware that we had been subject to a criminal fraud commonly referred to as “business email compromise fraud.” The incident involved unauthorized access to an employee’s email account by a third-party impersonator and resulted in an electronic payment of approximately $0.4 million intended for a vendor being fraudulently misdirected to unknown parties. We retained a third party to assist in our investigation of the incident and implementation of remedial measures, including enhancements to our controls relating to electronic payments to third parties. Approximately $0.2 million of the fraud loss was covered by insurance. We do not believe this incident had or will have a material impact on our business, financial condition or results of operations. However, cyber-related criminal activities continue to evolve and increase in frequency and sophistication, including as a result of advancements in generative artificial intelligence technology, and our security measures and controls may not be successful in preventing further cyber-related crimes.

Despite implementing security measures, any of the information technology systems belonging to us or our collaborators and third-party service providers and the sensitive and confidential information contained within them are vulnerable to damage or interruption from computer viruses and other malware, unauthorized access, including as a result of employee error (e.g., phishing or spoofing scams) or malfeasance, service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failure. We rely on third-party service providers and technologies for our data processing-related activities, including without limitation third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. In addition, we do not have our own information technology department or personnel and rely on third-party consultants and other service providers to establish and maintain our information technology infrastructure and systems, and they may fail to perform as expected. Moreover, the shift to remote working arrangements and the prevalent use of mobile devices that access sensitive or confidential

information increases the risk of data security breaches. Technology security systems and other security measures in employees' homes or other places they may work may not be as robust and more vulnerable to cybersecurity attacks. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party collaborators' or service providers' operations could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive or confidential information. A security incident or other interruption could disrupt our ability (or that of third parties upon which we rely) to conduct our business operations and could divert significant resources to remedy or mitigate the damage caused. For example, if clinical or nonclinical study data is lost or becomes compromised, it could result in delays in our product development and regulatory approval efforts and significantly increase our costs due to additional time and resources necessary to recover and verify, or potentially reproduce, the data. In addition, a security breach or privacy violation that leads to disclosure of personally identifiable information or protected health information could require us to make notifications to the public as well as regulatory authorities, harm our reputation, subject us to audit, investigation, steep fines and administrative penalties and mandatory corrective action. A data breach could also require us to verify the correctness of database contents and subject us to litigation, including class action lawsuits, or other liability under laws and regulations that protect personal data, consumer protection and other laws. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the internet, face the risk of systemic failure, which could disrupt our operations. If any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability, our product development programs and competitive position may be adversely affected, the further development of our product candidates may be delayed, and the manufacture and sale of any approved products may be impaired.

The costs related to significant security breaches or disruptions could be material, and, as was the case with the fraud discovered in March 2023, our insurance coverage may not cover all the losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations and product development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Moreover, if the information technology systems of our third-party collaborators, service providers or vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event.

***Our business may be adversely affected by unfavorable or unanticipated macroeconomic conditions and geopolitical events.***

Various macroeconomic factors could adversely affect our business, our results of operations and financial condition, including a U.S. government shutdown, delay or failure of the U.S. government to raise the federal debt ceiling, an increased rate of inflation, rising interest rates, adverse developments affecting financial institutions or the financial services industry, recessionary concerns and overall unfavorable economic conditions and uncertainties, including those resulting from geopolitical events, including the wars in Ukraine and the Middle East and strained relations between the U.S. and a number of foreign countries; international economic sanctions, including those imposed on Russia; climate change concerns; or public health emergencies, including the COVID-19 pandemic. U.S. government actions to reduce the federal deficit, or its delay or failure to raise the federal debt ceiling, may result in reduced funding for government-funded or subsidized health programs or require the federal government to stop or delay making payments on its obligations under such programs, which could impact sales of our products covered under such programs, if any, and negatively affect our operating results. Interest rates and the ability to access credit markets could adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute our products, if and when approved. Similarly, unfavorable or uncertain macroeconomic factors could affect the ability of our current or potential future collaborators, third-party service providers or suppliers, including sole source or single source manufacturers or 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 or allocate adequate resources to our products and product candidates could have a material adverse effect on our efforts to develop and obtain regulatory approvals for our product candidates and generate revenue from any approved products.

***We expect to continue to incur substantial costs and demands on management time to comply with laws and regulations affecting public companies.***

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. 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 corporate governance, disclosure and other reporting requirements of being a public company, and our management and other personnel, of whom we have a small number, will need to continue to devote substantial time towards compliance matters and initiatives.

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. Recent SEC rules and rulemaking initiatives, such as the new pay versus performance, cybersecurity, and climate-related disclosure requirements, may result in significant additional time and expense devoted to compliance initiatives.

***We are a smaller reporting company and a non-accelerated filer and the reduced disclosure requirements available to us 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 an 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.

***Our ability to use net operating loss carryforwards and other tax attributes to offset taxable income may be limited.***

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. At December 31, 2023, we had substantial federal and state net operating loss, or NOL, carryforwards. However, our federal NOL carryforwards and other tax attributes may not be available to offset future taxable income because of restrictions under U.S. tax law, and similar limitations may apply under state tax laws. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. See Note 7 “Income Taxes” to the accompanying consolidated financial statements for more information

about limitations on our ability to use our NOL carryforwards and other tax attributes. Such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected.

***An extended curtailment or halt of operations at the FDA, NIH, SEC and other government agencies, including due to a U.S. federal government shutdown, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and our ability to raise additional capital.***

Twice in the past decade, the previous appropriations legislation deadline was reached and Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U.S. government shutdowns that caused federal agencies to halt non-essential operations. The federal government came very close to another shutdown in late 2023. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. A federal government shutdown could prevent staff at federal agencies from performing key functions that may adversely affect our business. For example, disruptions at the FDA may delay meetings and other communications with agency staff necessary to progress development of our product candidates and may slow the time necessary for acceptance, review and approval of applications to commence clinical studies or to market a new product in the U.S. By way of further example, disruptions at the NIH, including its various institutes and centers, such as NICHD, could delay processing of new grant awards to fund research and development of potential new therapies or the disrupt staff's work and other activities or funding under active grant/cooperative agreements. If a prolonged government shutdown were to occur while our Phase 3 clinical study of Ovaprene is ongoing, depending on the amount of funds allocated and made available to the study before the shutdown begins, a federal government shutdown could adversely impact the ability of NICHD to carry out its responsibilities under our CRADA, including funding its share of the costs of the study, which could have a material adverse impact on our business and prospects. In addition, a government shutdown could prevent SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. While we currently have an effective shelf registration statement on Form S-3, a shelf registration statement on Form S-3 typically can only be used for three years, subject to a limited extension, and that three-year period for our current shelf S-3 registration statement ends on April 7, 2024. If a federal government shutdown halts non-essential SEC operations for an extended period, it may negatively impact our ability to raise additional capital through registered offerings of our securities in the future. If a prolonged U.S. government shutdown or other event or condition occurs that prevents the FDA, NIH, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, which could have a material adverse effect on our business.

**Risks Related to Ownership of Our Common Stock**

***The price of our common stock may rise and fall rapidly, substantial price fluctuations may occur regardless of developments in our business or our operating performance, and you could lose all or part of your investment as a result.***

The stock market in general, and the market for biopharmaceutical companies in particular, have experienced significant volatility, which has often been unrelated to the operating performance of particular companies. The stocks of small cap and microcap biopharmaceutical companies like ours tend to be highly volatile. Our common stock has experienced extreme trading price and volume fluctuations in the past, including fluctuations that have been unrelated or disproportionate to developments in our business and our operating performance, and we expect that our stock price will continue to experience high volatility. The market price for our common stock may be influenced by a variety of factors, some of which are beyond our control or are related in complex ways, including:

- significant developments with our product development programs, such as actual or anticipated changes to development and approval timelines, results from any clinical trial, unanticipated serious safety concerns, suspension or discontinuation of a program, initiation of new programs and communications or decisions from the FDA or other regulatory authorities relating to applications we submit for clinical trials or marketing approval of our product candidates, in each case particularly those related to our clinical-stage product candidates;
- announcements of capital raising transactions, including sales of our common stock or securities convertible into or exercisable for shares of our common stock by us, or expectation of additional financing efforts;
- the amount of our unrestricted cash;

- the level of actual or anticipated expenses related to development of our product candidates, and in particular our clinical-stage development programs;
- announcements relating to strategic collaborations or alliances or significant licenses, acquisitions or dispositions of assets by us or companies perceived to be comparable to us;
- 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 collaborations, joint ventures and capital commitments;
- additions or departures of key management or scientific personnel;
- significant developments with third-party products or product development programs perceived as competitive to ours, such as results of clinical trials, unanticipated serious safety concerns, suspension or discontinuation of a program, significant communications or decisions from the FDA or other regulatory authorities, introduction of new product candidates or new uses for existing products, commercial launch and product sales;
- significant business disruptions, including as a result of cybersecurity incidents, geopolitical events, including military conflicts, war, terrorism or economic conflicts, or natural disasters such as earthquakes, typhoons, floods and fires or public health emergencies such as the COVID-19 pandemic;
- events or conditions that affect the financial markets or U.S. or global economy in general, including geopolitical conflicts, potential or actual U.S. government shutdown or failure to raise the federal debt ceiling, economic slowdown or recession, increased inflation, and rising interest rates;
- regulatory or legal developments in the U.S. and other countries;
- changes in the structure of health care payment systems;
- developments or trends in the biopharmaceutical or women's health care industries;
- period to period fluctuations in our financial results;
- recommendations or reports issued by securities research analysts;
- increased selling by our stockholders, 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.

***If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.***

Our common stock is listed on The Nasdaq Capital Market. As previously reported, on July 19, 2023, we received a letter from the Listing Qualifications Department (the “Nasdaq Staff”) of the Nasdaq Stock Market (“Nasdaq”) notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). We were provided an initial period of 180 calendar days, or until January 16, 2024, to regain compliance with the Minimum Bid Price Requirement. On January 17, 2024, the Nasdaq Staff notified us that because we had not timely regained compliance with the Minimum Bid Price Requirement, our common stock was subject to delisting from The Nasdaq Capital Market unless we timely requested a hearing before Nasdaq’s Hearings Panel (the “Panel”) to appeal the Nasdaq Staff’s delisting determination. We submitted a timely request for a hearing before the Panel, which stayed the suspension and delisting of our common stock pending the decision of the Panel and the expiration of any extension period granted by the Panel.

On February 27, 2024, the Panel notified us that, based on its review of the written record, which included our commitment to effect a reverse stock split if necessary to regain compliance with the Minimum Bid Price Requirement, it determined to grant us a temporary exception until July 15, 2024 (the “Exception Period”) to regain compliance with the Minimum Bid Price Requirement. The Panel granted the temporary exception subject to us obtaining board of directors and stockholder approval for and effecting the reverse stock split on or before specified dates that would enable us to demonstrate compliance with the Minimum Bid Price Requirement by evidencing a closing bid price of $1.00 or more per share for a minimum of ten consecutive trading sessions on or before July 15, 2024. The Panel

advised us that, during the Exception Period, we must provide Nasdaq with prompt notification of any significant events that may affect our compliance with Nasdaq listing requirements, including any event that may call into question our ability to meet the terms of the temporary exception. The Panel also advised us that should we fail to meet any of the terms of the temporary exception, our common stock will immediately be delisted.

As of the date of this report, we have not regained compliance with the Minimum Bid Price Requirement. If we seek stockholder approval of a reverse stock split, there can be no assurance that our stockholders will approve it or, if approved and implemented, that we would be able to regain compliance with the Minimum Bid Price Requirement. There are many factors that affect the trading price of our common stock, including those described in this "Risk Factors" section, and many of those factors are outside of our control. Even if we demonstrate compliance with the Minimum Bid Price Requirement within the Exception Period, a reverse stock split may not result in any sustained increase in the trading price of our common stock and, as a result, we may not be able to maintain compliance with the Minimum Bid Price Requirement longer term.

There can be no assurance we will be able to satisfy all other continued listing requirements of the Nasdaq Capital Market and maintain the listing of our common stock on the Nasdaq Capital Market even if we regain compliance with the Minimum Bid Price Requirement. Other continued listing requirements include that we satisfy the requirements of at least one of the continued listing standards commonly referred to as the stockholders' equity rule, the market value of listed securities rule and the net income rule. The stockholders' equity rule requires that our stockholders' equity be at least $2.5 million, the market value of listed securities rule requires that the market value of our common stock be at least $35 million, and the net income rule requires that we have net income from continuing operations of $500,000 in our most recently completed fiscal year or in two of our three most recently completed fiscal years. Based on our stockholders' equity as of December 31, 2023 and our results of operations for our three most recently completed fiscal years, we do not satisfy the stockholders' equity rule or the net income rule. As of March 27, 2024, we did satisfy the market value of listed securities rule.

The suspension or delisting of our common stock, for whatever reason, could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the suspension or delisting of our common stock, for whatever reason, may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

***A reverse stock split could lead to a decrease in the overall market value of our common stock and adversely affect the liquidity of our common stock.***

A reverse stock split, if implemented, would reduce the number of outstanding shares of our common stock in proportion to the reverse split ratio and would have the immediate effect of proportionately increasing the per share price of our common stock. A reverse stock split is often viewed negatively by the market and, consequently, could lead to a decrease in our overall market value. If the per share trading price of our common stock does not increase in proportion to the reverse stock split ratio after the reverse stock split is implemented, then our overall market value (measured as the product of our outstanding shares of common stock and the per share trading price) will be less than before the reverse stock split. In some cases, the per share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse stock split levels. Accordingly, if we implement a reverse stock split, there can be no assurance that our overall market value will remain the same after the reverse stock split, or that the reverse stock split would not have an adverse effect on the trading price of our common stock due to the reduced number of shares that would be outstanding after the reverse stock split. Liquidity for our stockholders could be adversely affected by the reduced number of shares outstanding after a reverse stock split. A reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock. In addition, a reverse stock split may result in some stockholders owning "odd lots" of less than 100 shares. Odd lot shares may be more difficult to sell, and brokerage commissions and other costs of transactions in odd lots are generally somewhat higher than the costs of transactions in "round lots" of even multiples of 100 shares.

***The sale of our common stock in ATM offerings 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.***

We have used at-the-market, or ATM, offerings to fund a significant portion of our operations in recent years, and we may continue to use ATM offerings to raise additional capital in the future. For example, in 2021, we sold an aggregate of approximately 36.4 million shares of our common stock in ATM offerings. We sold substantially fewer shares in ATM offerings in 2022 and 2023, however, we may sell significant amounts of shares in ATM offerings again in the future. While sales of shares of our common stock in ATM offerings may enable us to raise capital at a lower cost compared with other types of equity financing transactions; 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 warrants and options as well as the issuance of shares pursuant to future equity awards under our stock incentive plan may result in significant dilution to our stockholders.***

As of December 31, 2023, we had outstanding warrants to purchase up to approximately 15.0 million shares of our common stock at a weighted average exercise price of $0.63 per share, outstanding options to purchase up to approximately 9.5 million shares of our common stock at a weighted average exercise price of $1.46 per share and approximately 6.7 million shares of our common stock remained available for future issuance under our stock incentive plan. The exercise of a significant portion of our outstanding warrants and options and the issuance of shares of our common stock pursuant to future equity awards under our stock incentive plan may result in significant dilution to our stockholders.

***Substantial future sales of our shares of common stock, or the perception that such sales could occur, may cause the price of our common stock to decline, even if our business is doing well.***

Sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, may adversely affect the trading price of our common stock, and may make it more difficult for existing stockholders to sell their shares of our common stock at a time and price they deem appropriate. We are unable to predict the effect that such sales may have on the trading price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity or equity-linked securities in the future at a time and at a price that we deem appropriate.

Shares underlying outstanding warrants represent approximately 15.0% of the outstanding shares of our common stock as of March 27, 2024, and the underlying shares generally may be freely sold into the public market following exercise of the warrants by the warrant holders. In addition, pursuant to the terms of the royalty interest financing agreement we entered into in December 2023, we may issue additional warrants to purchase up to an additional 7.0 million shares of our common stock with an exercise price of $0.3467 per share. Further, the issuance of all of the approximately 9.5 million shares of our common stock underlying outstanding options and the approximately 6.7 million shares of our common stock that remained available for future issuance under our stock incentive plan as of December 31, 2023 have been registered under the Securities Act and such shares if, and when issued, can be freely sold in the public market, 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.

Almost all of our outstanding warrants have exercise periods that extend into December 2028 or March 2029 and, as of December 31, 2023, our outstanding options had a weighted average remaining contractual exercise period of approximately 7.5 years. Accordingly, the potential adverse market and price pressures resulting from these sales, or the perception that such sales could occur, may continue for an extended period of time and continued negative pressure on the trading price of our common stock could have a material adverse effect on our ability to raise additional capital through equity or equity-linked financings. If, in the future, we issue additional shares of common stock, warrants or other equity or equity-linked securities in one or more transactions, at prices and in a manner we determine from time to time, in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise, any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

***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 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 Restated Certificate of Incorporation, as amended, our Third Amended and Restated By-Laws 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 in any annual election of directors or class of directors to amend or repeal our by-laws or certain provisions of our charter.

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.

***Provisions in our by-laws could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our Third Amended and Restated By-Laws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders; provided that, the exclusive forum provision will not apply to actions or suits brought to enforce any liability or duty created by the

Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. If any action that is required under our by-laws to be brought against us in Delaware is filed by a stockholder in a court other than a court located within Delaware, the stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within Delaware in connection with any action brought in any such court to enforce our Delaware forum selection provision and (ii) having service of process made upon the stockholder in any such enforcement action by service upon that stockholder's counsel, as agent for the stockholder. In addition, our by-laws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to these provisions.

Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act. We believe the forum selection provisions in our by-laws may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against us and/or our directors, officers and employees as it may limit any stockholder’s ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers or employees. The enforceability of similar choice of forum provisions in other companies’ charter documents has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a future court could find the choice of forum provisions contained in our by-laws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our by-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

***If we fail to attract or maintain 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. As of the date of this report, to our knowledge, five analysts cover our company. 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 1C. CYBERSECURITY**

**Risk Management and Strategy**

As is the case for other companies in our industry, we may be the target of cyberattacks and other cyber incidents and, therefore, cybersecurity is an important element of our overall enterprise risk management, or ERM, program. Our management performs a semi-annual assessment of enterprise-wide risks to help assess, identify, and manage existing and emerging risks for our company, including cybersecurity risks. Through our ERM program we assess the characteristics and circumstances of the evolving business environment at the time and seek to identify the potential impacts to our company of a particular risk.

Primary responsibility for assessing, identifying, and managing our cybersecurity risks rests with our management. To assist our management with such responsibility, we engage and consult with an external third party information technology consultant who reports to our Chief Accounting Officer. We also perform an annual cybersecurity assessment designed to help improve the systems and processes we have implemented designed to safeguard our information assets and operational integrity from cyber threats, protect employee information from unauthorized access or attack, as well as secure our networks and systems. Network and information systems and other technologies, including those related to our network management, are important to our business activities. As a result, we have multiple layers of security designed to detect and deter cybersecurity incidents. As part of our overall ERM program, we monitor and test our safeguards and train our employees on these safeguards, in certain instances with the assistance of our external third party information technology consultant. Personnel at all levels and

departments are made aware of our cybersecurity policies through trainings. We also maintain an incident response plan designed to respond to, mitigate and remediate cybersecurity incidents according to a defined set of severity ratings based on the potential impact to our business, information technology systems, network or data, including data held or information technology services provided by third-party vendors or other service providers.

As of the date of filing this report, we do not believe there are any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

For additional information regarding risks from cybersecurity threats, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K.

**Governance**

Our board of directors administers its cybersecurity risk oversight function through its audit committee. The audit committee is responsible for overseeing our policies, practices and assessments with respect to cybersecurity, and provides periodic updates to our board of directors. The audit committee receives periodic updates from management and our external third party information technology consultant regarding the effectiveness of the systems and processes we have implemented designed to safeguard our information assets and operational integrity from cyber threats, protect employee information from unauthorized access or attack, as well as secure our networks and systems, and regarding other cybersecurity matters, including the results from cybersecurity systems testing and any recent cybersecurity incidents and related responses. Our audit committee is also notified between such updates as soon as practicable regarding significant new cybersecurity threats or incidents. The audit committee also receives a report on cybersecurity matters and related risk exposures at least semi-annually from our Chief Accounting Officer. Many of our board members have achieved the National Association of Corporate Directors Carnegie Mellon University CERT Certification in Cybersecurity Oversight.

**ITEM 2. PROPERTIES**

We lease real property to support our business. We believe that the real property we lease is in good operating condition, meets our current needs and that we will be able to renew our lease when needed on acceptable terms or find alternative facilities. See Note 10 "Leased Properties" to the accompanying consolidated financial statements for more information about our real property leases.

**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 REGISTRANT'S COMMON EQUITY, 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 27, 2024, we had approximately 34 stockholders of record.

The number of stockholders of record is based upon the actual number of holders registered on our books at such date. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held by banks, brokers and other financial institutions.

**Dividend Policy**

We have never declared or paid cash dividends on our common stock. We currently do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws and contractual limitations, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

**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**

None.

### ITEM 6. [RESERVED.]

### 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 I "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 biopharmaceutical company committed to advancing innovative products for women’s health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility. 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, to take those candidates through mid to late-stage clinical development or regulatory approval, and to establish and leverage strategic collaborations to achieve commercialization. We and our wholly-owned subsidiaries operate in one business segment.

The first FDA-approved product to emerge from our portfolio of women's health product candidates is XACIATO (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe). XACIATO was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In March 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. Accordingly, our

potential future revenue from the commercialization of XACIATO will consist of royalties based on net sales and milestone payments from Organon. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023.

Our product pipeline includes diverse programs that target unmet needs in women's health in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility, and aim to expand treatment options, enhance outcomes and improve ease of use for women. We are primarily focused on progressing the development of our existing portfolio of product candidates. However, we also explore opportunities to expand our portfolio by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on women's health.

Our current portfolio includes five product candidates in advanced clinical development (Phase 2-ready to Phase 3):

- **Ovaprene®**, a hormone-free, monthly intravaginal contraceptive;
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the female genitalia on demand for the treatment of female sexual arousal disorder (FSAD);
- **DARE-HRT1**, an intravaginal ring designed to deliver both bio-identical estradiol and progesterone together, continuously over a 28-day period, for the treatment of moderate-to-severe vasomotor symptoms, as part of menopausal hormone therapy;
- **DARE-VVA1**, a proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of vulvar and vaginal atrophy associated with menopause; and
- **DARE-CIN**, a proprietary, fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia (CIN) and other human papillomavirus (HPV)-related pathologies.

Our portfolio also includes five product candidates in Phase 1 clinical development or that we believe are Phase 1-ready:

- **DARE-PDM1,** a proprietary hydrogel formulation of diclofenac, a nonsteroidal anti-inflammatory drug, for vaginal administration as a treatment for primary dysmenorrhea;
- **DARE-204** and **DARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively;
- **DARE-FRT1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth.

In addition, our portfolio includes five preclinical stage programs:

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **DARE-LBT**, a novel hydrogel formulation for vaginal delivery of live biotherapeutics to support vaginal health;
- **DARE-GML**, an intravaginally-delivered potential multi-target antimicrobial agent formulated with glycerol monolaurate (GML), which has shown broad antimicrobial activity, killing bacteria and viruses;
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- **DARE-PTB2**, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein.

The product candidates and potential product candidates in our portfolio will require review and approval from the FDA, or a comparable foreign regulatory authority, prior to being marketed or sold. See ITEM 1. "BUSINESS," in Part I of this report for additional information regarding our product and product candidates.

Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or regulatory approval. We expect our research and development expenses will continue to represent the majority of our operating expenses for at least the next twelve months. Until we secure additional capital to fund our operating needs, we will focus our resources primarily on advancement of Ovaprene and Sildenafil Cream. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 program for the next several years, but we also expect such expenses will be supported by non-dilutive funding provided under a grant agreement we entered into in June 2021.

As discussed below, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. We are also subject to a number of other risks common to biopharmaceutical companies, including, but not limited to, dependence on key employees, reliance on third-party collaborators, service providers and suppliers, being able to develop commercially viable products in a timely and cost-effective manner, dependence on intellectual property we own or in-license and the need to protect that intellectual property and maintain those license agreements, uncertainty of market acceptance of products, uncertainty of third-party payor coverage, pricing and reimbursement for products, rapid technology change, intense competition, compliance with government regulations, product liability claims, and exposure to cybersecurity threats and incidents.

The process of developing and obtaining regulatory approvals for prescription drug and drug/device products in the United States and in foreign jurisdictions is inherently uncertain and requires the expenditure of substantial financial resources without any guarantee of success. To the extent we receive regulatory approvals to market and sell our product candidates, the commercialization of any product and compliance with subsequently applicable laws and regulations requires the expenditure of further substantial financial resources without any guarantee of commercial success. The amount of post-approval financial resources required for commercialization and the potential revenue we may receive from sales of any product will vary significantly depending on many factors, including whether, and the extent to which, we establish our own sales and marketing capabilities and/or enter into and maintain commercial collaborations with third parties with established commercialization infrastructure.

**Recent Events**

***Sildenafil Cream Positive End-of-Phase 2b Meeting with FDA***

As discussed in ITEM 1. "BUSINESS" in Part I of this report, in January 2024, we announced the successful completion of an end-of-Phase 2 meeting with the FDA supporting advancement of Sildenafil Cream for the treatment of FSAD to Phase 3 clinical development.

***Noncompliance with Nasdaq's Minimum Bid Price Requirement***

On January 17, 2024, the Nasdaq Staff notified us that because we had not timely regained compliance with the Minimum Bid Price Requirement, our common stock was subject to delisting from The Nasdaq Capital Market unless we timely requested a hearing before the Nasdaq Hearings Panel, or the Panel, to appeal the Nasdaq Staff's delisting determination. We submitted a timely request for a hearing before the Panel, which stayed the suspension and delisting of our common stock pending the decision of the Panel and the expiration of any extension period granted by the Panel.

On February 27, 2024, the Panel notified us that, based on its review of the written record, which included our commitment to effect a reverse stock split if necessary to regain compliance with the Minimum Bid Price Requirement, it determined to grant us a temporary exception until July 15, 2024 (the "Exception Period") to regain compliance with the Minimum Bid Price Requirement. The Panel granted the temporary exception subject to us obtaining board of directors and stockholder approval for and effecting the reverse stock split on or before specified dates that would enable us to demonstrate compliance with the Minimum Bid Price Requirement by evidencing a closing bid price of $1.00 or more per share for a minimum of ten consecutive trading sessions on or before July 15, 2024. The Panel advised us that, during the Exception Period, we must provide Nasdaq with prompt notification of any significant events that may affect our compliance with Nasdaq listing requirements, including any event that may call into question our ability to meet the terms of the temporary exception. The Panel also advised us that should we fail to meet any of the terms of the temporary exception, our common stock will immediately be delisted.

***Receipt of Grant to Support Biotherapeutic Product Development***

On January 17, 2024, we entered into a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation, pursuant to which we received $750,000 in grant funding to gather and analyze data on the global bacterial biologic supply chain to help the Foundation identify potential contract manufacturing organization partners for manufacturing clinical and commercial supplies of bacteria-based biotherapeutic products.

***Royalty Interest Financing Agreement***

On December 21, 2023, we entered into a royalty interest financing agreement with United in Endeavour, LLC, or United, pursuant to which we sold to United an interest in royalty and milestone payments we receive from Organon based on net sales of XACIATO for a purchase price of up to $12 million. We received a payment of $5.0 million from United on the date of the agreement, and until December 31, 2026, we may, in our sole discretion, elect to receive up to three additional payments from United of up to an aggregate of $7 million. Pursuant to the terms of the agreement, on December 21, 2023, we issued to United a warrant to purchase up to 5.0 million shares of our common stock. In addition, for every additional $1.0 million payment we elect to receive from United under the agreement, we agreed to issue warrants to purchase up to 1.0 million shares of our common stock, for an aggregate of warrants to purchase up to 7.0 million shares of our common stock. The initial warrant has, and each additional warrant, if any, will have, an exercise price of $0.3467 per share, subject to customary adjustments, and is or will be exercisable, in full or in part, at any time from the date of issuance on or prior to the fifth anniversary of the date of issuance of the particular warrant. For more information, see ITEM 1. “BUSINESS— Royalty Interest Financing Agreement” in Part I of this report and Note 11 “Sale of Future Royalties” to the accompanying consolidated financial statements.

***Positive Topline Data from Phase 1 Clinical Study of DARE-PDM1***

As discussed in ITEM 1. "BUSINESS" in Part I of this report, on December 20, 2023, we announced positive topline data from our Phase 1 clinical study of DARE-PDM1.

**Financial Overview**

***Revenue***

To date we have generated approximately $12.8 million in revenue, all from payments received under our license agreement with Organon to commercialize XACIATO. In the future, we expect to continue to generate revenue from royalties based on the net sales of XACIATO and we may generate revenue from commercial milestones based on the net sales of XACIATO, from product sales of other approved products, if any, and from license fees, milestone payments, and research and development payments in connection with strategic collaborations. Our ability to generate such revenue, with respect to XACIATO, will depend on the extent to which its commercialization is successful, and with respect to our product candidates, will depend on their successful clinical development, the receipt of regulatory approvals to market such product candidates and the eventual successful commercialization of products. If XACIATO is not commercially successful or we fail to complete the development of our 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***

The majority of our operating expenses during a fiscal year are research and development expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. 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 clinical trial sites and consultants that conduct research and development and regulatory affairs 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;

- milestone payments due to third parties under acquisition and in-licensing arrangements we incur, or the incurrence of which we deem probable; and
- internal costs associated with activities performed by our research and development organization and generally benefit multiple programs.

Investment in the development of and seeking regulatory approval for our clinical-stage and Phase 1-ready product candidates and the development of any other potential product candidates we may advance into and through clinical trials in the pursuit of regulatory approvals, will increase our research and development expenses. Activities associated with the foregoing 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.

Until the first commercial sale of XACIATO, we recognized contract manufacturing expenses associated with producing commercial supplies of XACIATO and costs of regulatory affairs activities related to XACIATO as research and development expenses. Following the first commercial sale of XACIATO, and during the interim period when we were the NDA holder of XACIATO and provided commercial supplies of XACIATO to Organon, those expenses are recognized as general and administrative expenses.

We recognize the Australian Research and Development Tax Incentive Program, or the Tax Incentive, as a reduction of research and development expenses. The amounts are determined based on our eligible research and development expenditures and are non-refundable, provided that in order to qualify for the Tax Incentive the filing entity must have revenue of less than AUD $20.0 million during the tax year for which a reimbursement claim is made and cannot be controlled by an income tax exempt entity. The Tax Incentive is recognized when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured or reliably estimated.

We receive funding through grants that support activities related to the development of certain of our product candidates. As we incur eligible expenses under those grants, we recognize grant funding in the statements of operations as a reduction to research and development expenses (contra-research and development expense). For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies – Grant Funding, to our consolidated financial statements contained herein. For the years ended December 31, 2023 and 2022, we recognized contra-research and development expense of approximately $9.3 million and $5.6 million, respectively.

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 or 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.

***License Fee Expenses***

License fee expenses consist of up-front license fees and annual license fees due under our in-licensing arrangements.

***General and Administrative Expenses***

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services, commercial-readiness expenses, and royalty and milestone expenses. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs. Commercial-readiness expenses consist of consultant and advisor costs. Royalty and milestone expenses consist of payments we owe under our in-license agreements.

**Recently Issued Accounting Standards**

From time to time, the Financial Accounting Standards board, or FASB, or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification, or ASC, are communicated through issuance of an Accounting Standards Update. We have implemented all new accounting pronouncements that are in effect and that may impact our financial statements. We have evaluated recently issued

accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

**Critical Accounting Policies and Estimates**

Management's discussion and analysis of financial condition and results of operations is based on our consolidated 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 our financial statements. While our significant account policies are described in more detail in Note 2 to our consolidated financial statements included herein, we believe that the following accounting policies are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

***Revenue Recognition***

Under ASC Topic 606, or ASC 606, we recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, we perform five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy our performance obligations. At contract inception, we assess the goods or services agreed upon within each contract, assess whether each good or service is distinct, and determines those that are performance obligations. We then recognize as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, we develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

*Collaboration Revenues.* We enter into collaboration and licensing agreements under which we out-license certain rights to our products or product candidates to third parties. The terms of these arrangements typically include payment of one or more of the following to us: non-refundable, up-front license fees; development, regulatory and/or commercial milestone payments; and royalties on net sales of licensed products. To date, we have not recognized any collaboration revenues.

*License Fee Revenue.* If the license to our intellectual property is determined to be distinct from the other performance obligations identified in a contract, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. To date, we have recognized $11.0 million in license fee revenue, all from payments received under our license agreement with Organon to commercialize XACIATO.

*Milestones.* At the inception of each arrangement in which we are a licensor and that includes developmental, regulatory or commercial milestones, we evaluate whether achieving the milestones is considered probable and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments not within our control, such as where achievement of the specified milestone depends on activities of a third party or regulatory approval, are not considered probable of being achieved until the specified milestone occurs. To date, we have recognized $1.8 million of milestone revenue, which represents the $1.8 million

milestone payment we received under our license agreement with Organon in connection with the first commercial sale of XACIATO.

*Royalties.* For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have recognized approximately $7,900 of royalty revenue.

*Product Supply.* Arrangements that include a promise for future supply of product for commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. We evaluate whether we are the principal or agent in the arrangement based on the degree we control the specified product at any time before transfer to the customer. If we are in the capacity of a principal, revenues are recognized on a gross basis. If we are in the capacity of an agent, revenues are recognized on a net basis. To date, we have recognized approximately $205,000 in revenue (and $201,000 in other expense attributed to the cost of revenue) associated with our XACIATO product supply arrangement, which is recorded in other income in our consolidated statements of operations and comprehensive loss. In connection with the transfer of the NDA for XACIATO to Organon in December 2023, that arrangement was terminated and we will not recognize product supply revenue associated with that arrangement in the future.

***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 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 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.

Stock options or stock awards with performance conditions issued to non-employees who are not directors are measured on the grant date and recognized when the performance is complete. Refer to Note 9 to our consolidated financial statements included in this report for more information.

***Grant Funding***

We receive certain research and development funding under grants issued by the U.S. government and a not-for-profit foundation. In accordance with a policy we adopted in 2018, we recognize grant funding in the statements of operations as a reduction to research and development expense as the related costs are incurred to meet those obligations over the grant period. Grant funding payments received in advance of research and development expenses incurred are recorded as deferred grant funding liability in our consolidated balance sheets. For the years ended December 31, 2023 and December 31, 2022, there were no material adjustments to our prior period estimates of grant funded research and development expenses. Refer to Note 13 to our consolidated financial statements included in this report for more information.

***Clinical Trial Expense Accruals***

We estimate expenses resulting from our obligations under contracts with vendors, CROs and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided.

We record clinical trial expenses in the period in which services are performed and efforts are expended. We accrue for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We estimate accruals through financial models taking into account discussion with applicable personnel and outside service providers as to the progress of trials. During the course of a clinical trial, we may adjust our clinical accruals if actual results differ from our estimates. We estimate accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are dependent upon accurate reporting by CROs and other third-party vendors. Although we do not expect our estimates to differ materially from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or

too low for any particular period. For the years ended December 31, 2023 and December 31, 2022 there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

**Results of Operations**

***Comparison of the Years ended December 31, 2023 and 2022***

The following table summarizes our consolidated results of operations for the years ended December 31, 2023 and 2022, and the change in the applicable category in terms of dollars and percentage:

| | Years Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | $ | % |
| Revenue | | | | |
| License fee revenue | $ 1,000,000 | $ 10,000,000 | $ (9,000,000) | (90)% |
| Milestone revenue | 1,800,000 | — | 1,800,000 | — % |
| Royalty revenue | 7,885 | — | 7,885 | — % |
| Total revenue | 2,807,885 | 10,000,000 | (7,192,115) | (72)% |
| Operating expenses | | | | |
| General and administrative | $ 12,109,691 | $ 11,243,271 | $ 866,420 | 8 % |
| Research and development | 21,538,074 | 30,042,217 | (8,504,143) | (28)% |
| License fee expenses | 100,000 | 100,000 | — | — % |
| Total operating expenses | 33,747,765 | 41,385,488 | (7,637,723) | (18)% |
| Loss from operations | (30,939,880) | (31,385,488) | 445,608 | 1 % |
| Other income | 778,489 | 437,750 | 340,739 | 78 % |
| Net loss | $ (30,161,391) | $ (30,947,738) | $ 786,347 | (3)% |

***Revenues***

Revenues for the years ended December 31, 2023 and 2022 related to our license agreement with Organon to commercialize XACIATO. For 2023, we recognized $1.0 million in license fee revenue upon execution of the amendment to the license agreement in July 2023, $1.8 million in milestone revenue in connection with the first commercial sale of XACIATO, and approximately $7,900 in royalties from net sales of XACIATO in the fourth quarter. For 2022, we recognized $10.0 million in license fee revenue related to the transfer of the license and related know-how to Organon upon effectiveness of the license agreement in June 2022.

***General and administrative expenses***

The increase of approximately $0.9 million in general and administrative expenses from 2022 to 2023 was primarily attributable to (i) a $0.5 million commercial milestone due under our license agreement for XACIATO, (ii) $0.4 million of commercial-readiness expenses related to XACIATO, (iii) a one-time fraud loss of approximately $0.2 million, net of proceeds we received under an insurance policy, related to criminal fraud commonly referred to as "business email compromise fraud" to which we were subject, and (iv) an increase in stock-based compensation expense of approximately $0.2 million. The foregoing were partially offset by decreases in personnel costs of approximately $0.6 million due to decreased bonus expense, and general corporate overhead, including rent and facilities expenses, of approximately $26,000.

***Research and development expenses***

The decrease of approximately $8.5 million in research and development expenses from 2022 to 2023 was primarily attributable to decreases in (i) costs related to development activities for Sildenafil Cream of approximately $6.4 million, (ii) costs related to manufacturing and regulatory affairs activities for Ovaprene of approximately $2.0 million, (iii) costs related to development activities for XACIATO of approximately $0.2 million, (iv) rent and facilities expenses of approximately $0.1 million, and (v) costs related to development activities for our preclinical programs and other development expenses of approximately $69,000. Such decreases were partially offset by increases in (a) costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $0.2 million, and (b) stock-based compensation expense of approximately $0.1 million.

***License fee expenses***

For each of the years ended December 31, 2023 and December 31, 2022 we accrued or paid $100,000 of the annual license maintenance fee payable under our license agreement related to DARE-HRT1. For further discussion of this annual license maintenance fee, see Note 3 "Strategic Agreements— Strategic Agreements for Pipeline Development" to the accompanying consolidated financial statements.

***Other income***

The increase of $0.3 million in other income from 2022 to 2023 was primarily due to an increase in interest earned on cash balances in 2023 due to higher interest rates.

**Liquidity and Capital Resources**

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

At December 31, 2023, our accumulated deficit was approximately $171.2 million, our cash and cash equivalents were approximately $10.5 million, and our working capital deficit was approximately $2.9 million. We incurred a loss of approximately $30.2 million and had negative cash flow from operations of approximately $38.9 million for the year ended December 31, 2023.

Our cash and cash equivalents at December 31, 2023 represented funds received under grant agreements related to DARE-LARC1 and DARE-LBT and such funds may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. For additional information about these grant agreements, see "—Deferred Grant Funding" and "—Grant Agreements," below. We expect to incur significant losses from operations and negative cash flows from operations for the foreseeable future as we continue to develop and seek to bring to market our product candidates.

The majority of our operating expenses during a fiscal year are research and development expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. In large part, we can control the pace of advancement of our development programs and therefore, we can control the timing of when we incur most of our research and development expenses. We expect our primary uses of capital 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 to third-party licensors upon the occurrence of commercial milestones for XACIATO and development milestones for our product candidates pursuant to terms of the agreements under which we acquired or in-licensed rights to those programs, legal expenses, other regulatory expenses and general overhead costs. Our future funding requirements could also include significant costs related to commercialization of our product candidates, if approved, depending on the type, nature and terms of commercial collaborations we establish, and in particular, if we determine to engage in commercialization activities directly as opposed to through a third-party collaborator. We anticipate our general and administrative expenses for 2024 will be consistent with our general and administrative expenses for 2023.

Under the royalty interest financing agreement we entered into in December 2023, we may, in our sole discretion, elect to receive up to an additional aggregate amount of $7.0 million. Under our license agreement relating to XACIATO, we may receive royalty payments based on net sales of XACIATO, however, we do not expect such royalty payments for 2024 to materially impact our cash resources or requirements.

We closely monitor our limited cash resources and we have implemented cost-savings measures, primarily by controlling our spend on research and development activities related to clinical-stage programs other than Ovaprene and Sildenafil Cream. Our research and development expenses for 2024, until we secure additional capital to fund our operating needs, will continue to be primarily associated with manufacturing activities in connection with our ongoing pivotal Phase 3 clinical study of Ovaprene and activities, including regulatory affairs activities, related to advancing Sildenafil Cream toward a Phase 3 clinical study. However, we plan to continue to advance preclinical development of DARE-LARC1, the costs of which are being supported by grant funding.

We will need additional capital to fund our operating needs into the third quarter of 2024 and to meet our current obligations as they become due. We are in ongoing discussions with multiple potential third-party sources of additional capital, including non-dilutive sources of capital. Many aspects of our ability to obtain additional capital are not entirely within our control and there can be no assurance that we will receive additional capital when needed, on

favorable terms, or at all. 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 the risk factor in Item 1A of Part I of this report titled, *We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.*

Historically, the cash used to fund our operations has come from a variety of sources and predominantly from sales of shares of our common stock. We have also received a significant amount of cash through non-dilutive grants and strategic collaborations. We will continue to evaluate and may pursue a variety of capital raising options on an on-going basis, including sales of equity (including sales of our common stock in ATM offerings), debt financings, government or other grant funding, collaborations, structured financings, and strategic alliances or other similar types of arrangements, to cover our operating expenses, and the cost of any license or other acquisition of new product candidates or technologies. 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. Our ability to raise capital through sales of our common stock will depend on a variety of factors including, among others, market conditions, the trading price and volume of our common stock, our clinical and commercial developments, and investor sentiment. In addition, macroeconomic factors and volatility in the financial market, which may be exacerbated in the short term by concerns over inflation, interest rates, economic recession, adverse developments affecting financial institutions or the financial services industry, impacts of the wars in Ukraine and the Middle East, strained relations between the U.S. and several other countries, and social and political discord and unrest in the U.S., among other things, may make equity or debt financings more difficult, more costly or more dilutive to our stockholders, and may increase competition for, or limit the availability of, funding from other potential third-party sources of capital, such as strategic collaborators and sources of grant funding.

In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders, and debt financings may subject us to restrictive covenants, operational restrictions and security interests in our assets. If we raise capital through collaborations, structured financings, strategic alliances or other similar types of arrangements, we may be required to relinquish some or all of our rights to potential revenue or to intellectual property rights for our product candidates on terms that are not favorable to us.

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. As discussed above, there is substantial doubt about our ability to continue as a going concern. The accompanying consolidated 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.

***Deferred Grant Funding***

We have received substantial funding under grant agreements related to DARE-LARC1 and DARE-LBT. Under these agreements, and under the agreement we received from the Foundation in January 2024 to fund activities related to bacteria-based live biotherapeutic product development, we generally receive grant funds before we incur the eligible expenses. Funds received that have not been spent are recorded both as cash and cash equivalents and as a deferred grant funding liability in our consolidated balance sheets. Our deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. As of December 31, 2023, our deferred grant funding liability was approximately $13.7 million, which primarily consisted of unspent funds for the DARE-LARC1 program. The balance of our deferred grant funding liability at December 31, 2023 primarily consisted of funds for the DARE-LARC1 program that have been spent but not yet expensed in accordance with GAAP. For more information about these grant agreements, see "—Grant Agreements" below, and Note 2, Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding, and Note 13, Grant Awards-Other Non-Dilutive Grant Funding to the accompanying consolidated financial statements.

***Cash Flows***

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

| | Years Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Net cash used in operating activities | $ (38,856,654) | $ (18,088,429) |
| Net cash used in investing activities | (629,430) | (63,069) |
| Net cash provided by financing activities | 15,637,120 | 1,343,354 |
| Effect of exchange rate changes on cash and cash equivalents | (9,585) | (196,338) |
| Net decrease in cash | $ (23,858,549) | $ (17,004,482) |

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

Cash used in operating activities during the year ended December 31, 2023 included the net loss of $30.2 million, decreased by non-cash stock-based compensation expense of approximately $2.5 million. Components providing operating cash were an increase in accounts payable of approximately $1.4 million, a decrease in other receivables of approximately $0.8 million, and a decrease in prepaid expenses of approximately $0.5 million. Components reducing operating cash were a decrease in accrued expenses of approximately $8.3 million, a decrease in deferred grant funding of approximately $4.6 million, an increase in deposits of $1.2 million primarily related to deposits paid for the construction of capital equipment, and a decrease in other non-current assets of approximately $10,000.

Cash used in operating activities during the year ended December 31, 2022 included the net loss of $30.9 million, decreased by non-cash stock-based compensation expense of approximately $2.2 million. Components providing operating cash were an increase in accrued expenses of approximately $7.8 million, and an increase in deferred grant funding of approximately $7.8 million. Components reducing operating cash were an increase in prepaid expenses of approximately $4.2 million, an increase in other receivables of approximately $0.6 million, and a decrease in accounts payable of approximately $75,000.

***Net cash used in investing activities***

Cash used in investing activities during the years ended December 31, 2023 and December 31, 2022 was related to purchases of property and equipment of approximately $629,000 and $63,000, respectively.

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

Cash provided by financing activities during the year ended December 31, 2023 consisted of proceeds from (i) the sale of our common stock and warrants in the registered direct offering completed in September 2023 of approximately $7.0 million, (ii) the sale of future royalties of approximately $4.7 million, net, (iii) the sales of our common stock under our ATM sales agreement of approximately $2.3 million, net, (iv) the exercise of warrants of approximately $1.3 million, and (v) the financing of certain director and officer and other liability insurance premiums of approximately $0.6 million net of payments made of approximately $0.3 million.

Cash provided by financing activities of during the year ended December 31, 2022 consisted primarily of net proceeds from sales of our common stock under our ATM sales agreement.

***License and Royalty Agreements***

We agreed to make royalty and milestone payments under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream, and under other agreements related to our other clinical and preclinical candidates. During 2024, based on our current expectations regarding the development of our product candidates and sales of XACIATO, we expect to pay approximately $2.8 million in royalty and milestone payments under the license and development agreements. For further discussion of these potential payments, see Note 3 "Strategic Agreements—Strategic Agreements for Pipeline Development" to the accompanying consolidated financial statements.

***Grant Agreements***

We have received substantial funding under grant agreements related to DARE-LARC1 and DARE-LBT. In September 2023, following an assessment of our activities and the milestones we achieved to date, we received $4.5

million as the latest installment under the grant agreement to advance the preclinical development of DARE-LARC1. Grant funds under these agreements, and under the agreement we received from the Foundation in January 2024 to fund activities related to bacteria-based live biotherapeutic product development, generally are received before we incur the eligible expenses. Unspent grant funds are recorded as deferred grant funding liability in our consolidated balance sheets and our deferred grant funding liability as of December 31, 2023 primarily consisted of unspent grant funds for the DARE-LARC1 program. For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding, and Note 13, Grant Awards-Other Non-Dilutive Grant Funding to the accompanying consolidated financial statements.

***Other Contractual Obligations***

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

**Off-Balance Sheet Arrangements**

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

**ITEM 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 AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) 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 principal executive and financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on an evaluation, performed under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of our disclosure controls and procedures, our principal executive and 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, 2023 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, 2023 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, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

(a) None.

(b) During the period from October 1, 2023 to December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in the Company's 2024 Proxy Statement and is incorporated in this report by reference.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the Company's 2024 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 included in the Company's 2024 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 included in the Company's 2024 Proxy Statement and is incorporated in this report by reference.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the Company's 2024 Proxy Statement and is incorporated in this report by reference.

## PART IV

### ITEM 15. EXHIBITS AND 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**

Exhibits not filed or furnished herewith are incorporated by reference to exhibits previously filed with the SEC, as reflected in the table below. We will furnish a copy of any exhibit to stockholders, without charge upon written request to Daré Bioscience, Inc., 3655 Nobel Drive, Suite 260, San Diego, CA 92122, or by calling 858-926-7655.

| | | Incorporated by Reference | | | | |
|---|---|---|---|---|---|---|
| **Exhibit Number** | **Description of Exhibit** | **Form** | **File No.** | **Filing Date** | **Exhibit No.** | **Filed Herewith** |
| *PLANS OF ACQUISITION* | | | | | | |
| 2.1§ 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 | |
| 2.2+ | 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 | |
| *ARTICLES OF INCORPORATION AND BYLAWS* | | | | | | |
| 3.1 | Restated Certificate of Incorporation, as amended to date | 10-Q | 001-36395 | 08/09/2022 | 3.1 | |
| 3.2 | Third Amended and Restated By-Laws (as amended through January 24, 2023) | 10-Q | 001-36395 | 8/10/2023 | 3.1 | |
| *INSTRUMENTS DEFINING RIGHTS OF SECURITY HOLDERS* | | | | | | |
| 4.1 | Specimen stock certificate evidencing the shares of common stock | 10-K | 001-36395 | 03/28/2018 | 4.1 | |
| 4.2 | Warrant Agreement to purchase shares of common stock of the registrant with Aquilo Partners, L.P., entered into as of October 16, 2016. | 10-K | 001-36395 | 03/31/2022 | 4.2 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 4.3 | Form of common stock purchase warrants issued on September 1, 2023 | 8-K | 0001-36395 | 08/30/2023 | 4.1 | |
| 4.4 | Form of common stock purchase warrants issued on December 21, 2023 | | | | | X |
| 4.5 | Description of securities of the registrant | 10-K | 001-36395 | 03/27/2020 | 4.6 | |
| *COMMERCIAL AGREEMENTS* | | | | | | |
| 10.1(a)+ | Exclusive License Agreement dated March 31, 2022 between Organon International GmbH and Dare Bioscience, Inc., effective as of June 30, 2022 | 10-Q | 001-36395 | 05/12/2022 | 10.1 | |
| 10.1(b)+ | First Amendment to License Agreement by and between Organon International GmbH and Dare Bioscience, Inc. entered into as of July 4, 2023 | 10-Q | 0001-36395 | 11/09/2023 | 10.2 | |
| 10.2+ | Consent, Waiver and Stand-By License Agreement, dated March 30, 2022, by and among TriLogic Pharma, LLC, and MilanaPharm LLC, Dare Bioscience, Inc., and Organon International GmbH. | 10-Q | 001-36395 | 05/12/2022 | 10.2 | |
| 10.3Δ | 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 | |
| 10.4Δ | License Agreement dated March 19, 2017, between Daré Bioscience Operations, Inc. and ADVA-Tec, Inc. | 10-Q | 001-36395 | 11/13/2017 | 10.1 | |
| 10.5Δ | 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 | |
| 10.6(a)Δ | Amended and Restated Exclusive License Agreement for Atrophic Vaginitis Technology, effective as of July 14, 2006, dated August 15, 2007, 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 | |

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|---|---|---|---|---|---|
| 10.6(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 |
| 10.6(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 |
| 10.6(d)+ | Amendment No. 3 to the Amended and Restated Exclusive License Agreement, effective 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-K | 001-36395 | 3/30/2023 | 10.6(d) |
| 10.6(e)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 |
| 10.6(f)Δ | Exclusive License Agreement, effective 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 |
| 10.7(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) |
| 10.7(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) |
| 10.7(c) | Amendment No. 1 to Assignment Agreement entered into as of December 4, 2019 between Daré Bioscience, Inc. and Hammock Pharmaceuticals, Inc. | 10-K | 001-36395 | 03/27/2020 | 10.10(c) |
| 10.7(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 | 10-K | 001-36395 | 03/27/2020 | 10.10(d) |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.7(e) | Amendment to License Agreement effective as of September 21, 2021 by and among Daré Bioscience, Inc., TriLogic Pharma, LLC and MilanaPharm LLC | 10-Q | 001-36395 | 11/10/2021 | 10.1 | |
| 10.8+ | License Agreement dated as of January 10, 2020 between Bayer HealthCare LLC and Daré Bioscience, Inc. | 10-K | 001-36395 | 03/27/2020 | 10.16 | |
| 10.9+ | Grant Agreement between Daré Bioscience, Inc. and the Bill & Melinda Gates Foundation effective as of June 30, 2021 | 10-Q | 001-36395 | 08/12/2021 | 10.1 | |
| 10.10+ | Cooperative Research and Development Agreement entered into as of July 8, 2021 between Daré Bioscience, Inc. and the Eunice Kennedy Shriver National Institutes of Child Health and Human Development Institute | 10-Q | 001-36395 | 11/10/2021 | 10.2 | |
| 10.11 | Form of Securities Purchase Agreement dated as of August 29, 2023, between Dare Bioscience, Inc. and each purchaser identified on the signature pages thereto | 8-K | 0001-36395 | 08/30/2023 | 10.1 | |
| 10.12 | Royalty Interest Financing Agreement entered into as of December 21, 2023 between Dare Bioscience, Inc. and United in Endeavor, LLC | | | | | X |
| *MANAGEMENT CONTRACTS AND COMPENSATORY PLANS* | | | | | | |
| 10.13(a)* | Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan | 8-K | 001-36395 | 7/12/2018 | 10.1 | |
| 10.13(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 | 8/13/2018 | 10.3 | |
| 10.13(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 | 8/13/2018 | 10.4 | |
| 10.14* | 2014 Employee Stock Purchase Plan | S-1/A | 333-194442 | 3/31/2014 | 10.26 | |
| 10.15(a)* | Daré Bioscience, Inc. 2022 Stock Incentive Plan | 8-K | 001-36395 | 6/24/2022 | 10.1(a) | |
| 10.15(b)* | Form of Incentive Stock Option Agreement for Grants under the Daré Bioscience, Inc. 2022 Stock Incentive Plan | 8-K | 001-36395 | 6/24/2022 | 10.1(b) | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.15(c)* | Form of Nonstatutory Stock Option Agreement for Grants under the Daré Bioscience, Inc. 2022 Stock Incentive Plan | 8-K | 001-36395 | 6/24/2022 | 10.2(c) | |
| 10.16* | Daré Bioscience, Inc. Performance Bonus Plan, as amended | 10-Q | 001-36395 | 11/9/2023 | 10.3 | |
| 10.17* | Form of indemnification agreement between the registrant and each of its executive officers and directors | S-1 | 333-194442 | 03/10/2014 | 10.16 | |
| 10.18* | Amended and Restated Non-Employee Director Compensation Policy (as amended through January 2022) | 10-Q | 001-36395 | 5/12/2022 | 10.3 | |
| 10.19(a)* | 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 | |
| 10.19(b)* | Amendment No. 1 to Employment Agreement between Daré Bioscience, Inc. and Sabrina Martucci Johnson dated as of March 9, 2020 | 10-Q | 001-36395 | 05/14/2020 | 10.13(b) | |
| 10.20(a)* | 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 | |
| 10.20(b)* | Amendment No. 1 to Employment Agreement between Daré Bioscience, Inc. and Lisa Walters-Hoffert dated as of March 9, 2020 | 10-Q | 001-36395 | 05/14/2020 | 10.14(b) | |
| 10.21* | Daré Bioscience, Inc. Employment Offer Letter to John Fair, dated April 24, 2018 | S-1 | 333-251599 | 01/05/2021 | 10.19 | |
| 10.22* | Daré Bioscience, Inc. Change in Control Policy (effective October 15, 2019) | S-1 | 333-251599 | 01/05/2021 | 10.20 | |
| *OTHER EXHIBITS* | | | | | | |
| 21.1 | Subsidiaries of the registrant | | | | | X |
| 23.1 | Consent of Haskell & White LLP | | | | | X |
| 23.2 | Consent of Mayer Hoffman McCann P.C. | | | | | X |
| 31.1 | Certification of Principal Executive Officer and 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 and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | X |
| 97* | Dare Bioscience, Inc. Policy on Recovery of Erroneously Awarded Compensation | 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 |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) | 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 28, 2024

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<br>Sabrina Martucci Johnson | President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer) and Director | March 28, 2024 |
| /s/ MARDEE HARING-LAYTON<br>MarDee Haring-Layton | Chief Accounting Officer (Principal Accounting Officer) | March 28, 2024 |
| /s/ WILLIAM H. RASTETTER<br>William H. Rastetter, Ph.D. | Chairman of the Board and Director | March 28, 2024 |
| /s/ CHERYL R. BLANCHARD<br>Cheryl R. Blanchard, Ph.D. | Director | March 28, 2024 |
| /s/ JESSICA D. GROSSMAN<br>Jessica D. Grossman, M.D. | Director | March 28, 2024 |
| /s/ SUSAN L. KELLEY<br>Susan L. Kelley, M.D. | Director | March 28, 2024 |
| /s/ GREGORY W. MATZ<br>Gregory W. Matz, CPA | Director | March 28, 2024 |
| /s/ SOPHIA ONONYE-ONYIA<br>Sophia Ononye-Onyia, Ph.D. | Director | March 28, 2024 |
| /s/ ROBIN STEELE<br>Robin Steele, J.D., L.L.M. | Director | March 28, 2024 |

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

**Report of Independent Registered Public Accounting Firm**

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

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of **Daré Bioscience, Inc.** and Subsidiaries (the "Company") as of December 31, 2023, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year then ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023, and the consolidated results of its operations and its cash flows for the year then ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

**The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has 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 also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit 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 consolidated 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

**Report of Independent Registered Public Accounting Firm (Continued)**

**Critical Audit Matter**

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

We have served as the Company's auditor since 2023.

Irvine, California

March 28, 2024

**Report of Independent Registered Public Accounting Firm**

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

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of **Daré Bioscience, Inc.** and Subsidiaries ("Company") as of December 31, 2022, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2022, 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, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, 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 2 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 also described in Note 2 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 the 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 audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

**Critical Audit Matters**

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

We served as the Company's auditor from 2017 to 2023.

/s/ Mayer Hoffman McCann P.C.

March 30, 2023
San Diego, California

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Assets** | | |
| Current Assets | | |
| Cash and cash equivalents | $ 10,476,056 | $ 34,669,605 |
| Other receivables | 949,211 | 1,703,160 |
| Prepaid expenses | 6,118,272 | 6,665,988 |
| **Total current assets** | 17,543,539 | 43,038,753 |
| Property and equipment, net | 655,975 | 64,908 |
| Deposits | 1,163,477 | 10,502 |
| Operating lease right-of-use assets | 1,319,630 | 457,925 |
| Other non-current assets | 599,594 | 254,295 |
| **Total assets** | $ 21,282,215 | $ 43,826,383 |
| **Liabilities and stockholders' equity (deficit)** | | |
| **Current Liabilities** | | |
| Accounts payable | $ 3,385,551 | $ 2,027,953 |
| Accrued expenses | 2,889,005 | 10,894,016 |
| Deferred grant funding | 13,737,154 | 18,303,567 |
| Current portion of lease liabilities | 468,726 | 398,391 |
| **Total current liabilities** | 20,480,436 | 31,623,927 |
| Deferred revenue, non-current | 1,000,000 | 1,000,000 |
| Liability related to the sale of future royalties, net | 3,913,676 | — |
| Lease liabilities long-term | 935,743 | 90,346 |
| **Total liabilities** | 26,329,855 | 32,714,273 |
| Commitments and contingencies (Note 12) | | |
| **Stockholders' equity (deficit)** | | |
| Preferred stock, $ 0.01 par value, 5,000,000 shares authorized | | |
| None issued and outstanding | — | — |
| Common stock, $ 0.0001 par value, 240,000,000 shares authorized, 99,973,932 and 84,825,481 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively | 9,997 | 8,482 |
| Additional paid-in capital | 166,539,290 | 152,529,579 |
| Accumulated other comprehensive loss | ( 360,896 ) | ( 351,311 ) |
| Accumulated deficit | ( 171,236,031 ) | ( 141,074,640 ) |
| **Total stockholders' equity (deficit)** | ( 5,047,640 ) | 11,112,110 |
| **Total liabilities and stockholders' equity (deficit)** | $ 21,282,215 | $ 43,826,383 |

*See accompanying notes.*

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

| | Years Ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Revenue** | | |
| License fee revenue | $ 1,000,000 | $ 10,000,000 |
| Milestone revenue | 1,800,000 | — |
| Royalty revenue | 7,885 | — |
| **Total revenue** | 2,807,885 | 10,000,000 |
| **Operating expenses** | | |
| General and administrative | 12,109,691 | 11,243,271 |
| Research and development | 21,538,074 | 30,042,217 |
| License fee expense | 100,000 | 100,000 |
| **Total operating expenses** | 33,747,765 | 41,385,488 |
| **Loss from operations** | ( 30,939,880 ) | ( 31,385,488 ) |
| Other income | 778,489 | 437,750 |
| **Net loss** | $ ( 30,161,391 ) | $ ( 30,947,738 ) |
| **Net loss to common stockholders** | $ ( 30,161,391 ) | $ ( 30,947,738 ) |
| Foreign currency translation adjustments | ( 9,585 ) | ( 196,338 ) |
| **Comprehensive loss** | $ ( 30,170,976 ) | $ ( 31,144,076 ) |
| Loss per common share - basic and diluted | $ ( 0.35 ) | $ ( 0.37 ) |
| Weighted average number of common shares outstanding: | | |
| Basic and diluted | 87,303,701 | 84,571,805 |

*See accompanying notes.*

**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, 2021** | **83,944,119** | **$ 8,394** | **$ 149,027,802** | **$ ( 154,973 )** | **$ ( 110,126,902 )** | **$ 38,754,321** |
| Stock-based compensation | — | — | 2,158,511 | — | — | 2,158,511 |
| Issuance of common stock, net of issuance costs | 751,040 | 75 | 1,218,675 | — | — | 1,218,750 |
| Stock options exercised | 130,322 | 13 | 124,591 | — | — | 124,604 |
| Net loss | — | — | — | — | ( 30,947,738 ) | ( 30,947,738 ) |
| Foreign currency translation adjustments | — | — | — | ( 196,338 ) | — | ( 196,338 ) |
| **Balance at December 31, 2022** | **84,825,481** | **$ 8,482** | **$ 152,529,579** | **$ ( 351,311 )** | **$ ( 141,074,640 )** | **$ 11,112,110** |
| Stock-based compensation | — | — | 2,530,684 | — | — | 2,530,684 |
| Issuance of common stock from the exercise of warrants | 1,353,515 | 136 | 1,299,240 | — | — | 1,299,376 |
| Issuance of common stock, net of issuance costs | 13,794,936 | 1,379 | 9,345,277 | — | — | 9,346,656 |
| Issuance of common stock warrants, net of issuance costs | — | — | 834,510 | — | — | 834,510 |
| Net loss | — | — | — | — | ( 30,161,391 ) | ( 30,161,391 ) |
| Foreign currency translation adjustments | — | — | — | ( 9,585 ) | — | ( 9,585 ) |
| **Balance at December 31, 2023** | **99,973,932** | **$ 9,997** | **$ 166,539,290** | **$ ( 360,896 )** | **$ ( 171,236,031 )** | **$ ( 5,047,640 )** |

*See accompanying notes.*

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

| | Years Ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Cash flows from operating activities** | | |
| Net loss | $ ( 30,161,391 ) | $ ( 30,947,738 ) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | 38,363 | 24,202 |
| Stock-based compensation expense | 2,530,684 | 2,158,511 |
| Non-cash operating lease cost | 54,027 | 23,415 |
| Gain on early termination of lease | — | ( 46,477 ) |
| Non-cash interest expense on liability related to sale of future royalties | 24,289 | — |
| Changes in operating assets and liabilities: | | |
| Other receivables | 753,948 | ( 557,842 ) |
| Prepaid expenses | 547,714 | ( 4,189,376 ) |
| Deposits | ( 1,152,974 ) | — |
| Other non-current assets | ( 10,300 ) | 3,650 |
| Accounts payable | 1,357,600 | ( 75,132 ) |
| Accrued expenses | ( 8,272,201 ) | 7,757,774 |
| Deferred grant funding | ( 4,566,413 ) | 7,760,584 |
| Net cash used in operating activities | ( 38,856,654 ) | ( 18,088,429 ) |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | ( 629,430 ) | ( 63,069 ) |
| Net cash used in investing activities | ( 629,430 ) | ( 63,069 ) |
| **Cash flows from financing activities** | | |
| Net proceeds from issuance of common stock | 9,346,656 | 1,218,750 |
| Proceeds from the exercise of stock options | — | 124,604 |
| Proceeds from the exercise of common stock warrants | 1,299,376 | — |
| Proceeds from the sale of future royalties, net | 4,723,899 | — |
| Issuance of note payable | 601,174 | — |
| Payments on note payable | ( 333,985 ) | — |
| Net cash provided by financing activities | 15,637,120 | 1,343,354 |
| Effect of exchange rate changes on cash and cash equivalents and restricted cash | ( 9,585 ) | ( 196,338 ) |
| Net change in cash, cash equivalents and restricted cash | ( 23,858,549 ) | ( 17,004,482 ) |
| Cash, cash equivalents and restricted cash, beginning of year | 34,669,605 | 51,674,087 |
| Cash, cash equivalents and restricted cash, end of year | $ 10,811,056 | $ 34,669,605 |
| **Reconciliation of cash, cash equivalents and restricted cash to amounts reported in the consolidated balance sheets:** | | |
| Cash and cash equivalents | $ 10,476,056 | $ 34,669,605 |
| Restricted cash included in other non-current assets | 335,000 | — |
| **Total cash, cash equivalents and restricted cash** | $ 10,811,056 | $ 34,669,605 |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Operating right-of-use assets obtained in exchange for new operating lease liabilities | $ 1,291,425 | $ 585,942 |
| Issuance cost recorded under additional-paid-in-capital | $ 834,510 | $ — |

*See accompanying notes.*

## 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

***Organization and business***

Daré Bioscience, Inc. is a biopharmaceutical company committed to advancing 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 began assembling its diverse portfolio in 2017 through acquisitions, exclusive in-licenses and other collaborations. The Company's programs target unmet needs in women's health in the areas of contraception, vaginal health, reproductive health, menopause, sexual health, and fertility, and aim to expand treatment options, enhance outcomes and improve ease of use for women.

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

The Company's portfolio includes drug and drug/device product candidates and potential product candidates in various stages of development.

The first U.S. Food and Drug Administration (FDA)-approved product to emerge from the Company's portfolio of women's health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO. In March 2022, the Company entered into an exclusive global license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO, which became fully effective in June 2022. Under the license agreement, Organon (and/or its affiliates, agents or sublicensees) is solely responsible for the marketing, distribution and sale of XACIATO in the United States (and outside the U.S. if approved in non-U.S. jurisdictions in the future).

## 2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

***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.

***Cash, Cash Equivalents and Restricted Cash***

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 has an aggregate of approximately $0.3 million in restricted cash as of December 31, 2023, related to (i) letters of credit established under real property leases for the Company's wholly-owned subsidiary, Dare MB Inc., that serve as security for potential future default of lease payments, and (ii) collateralized cash for the Company's credit cards. The restricted cash is unavailable for withdrawal or for general obligations and is included in other non-current assets on the Company's consolidated balance sheet.

***Going Concern***

The Company 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 to continue for the foreseeable future, and expects that its net losses will continue for at least the next several years as it develops and seeks to bring to market its existing product candidates and seeks to potentially acquire, license and 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 reclassification 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.

At December 31, 2023, the Company had an accumulated deficit of approximately $ 171.2 million, cash and cash equivalents of approximately $ 10.5 million, deferred grant funding liabilities under the Company's grant agreements related to DARE-LARC1 and DARE-LBT of approximately $ 13.7 million, and a working capital deficit of approximately $ 2.9 million. The Company's cash and cash equivalents at December 31, 2023 represented grant funds received under such grant agreements that may be applied solely toward direct costs for the development of DARE-LARC1 and DARE-LBT, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support the entire operations of the Company. For the year ended December 31, 2023, the Company incurred a net loss of $ 30.2 million and had negative cash flow from operations of approximately $ 38.9 million.

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 will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current strategy.

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its 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 Company's consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

***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.

***Reclassification of Prior Year Presentation***

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

***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 Foundation. Under the Foundation grant, which the Company considers to be a research and development contract under FASB Accounting Standards Codification, or ASC, Topic 730 *Research and Development*, the Company granted the Foundation a Humanitarian License which gives the Foundation the right to make the funded developments accessible at an affordable price to people within developing countries. Grants received by the Company that do not require the transfer of goods or services to a customer are accounted for by analogy to International Accounting Standards 20, *Accounting for Grants and Disclosure of Government Assistance*, or IAS 20. Under IAS 20, the Company recognizes grant funding in the statements 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, 2023 and December 31, 2022, the Company recognized approximately $ 9.3 million and $ 5.6 million, respectively, in the statements 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 funding 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 and assumptions reflected in these consolidated financial statements include, but are not limited to, management's judgments with respect to its revenue arrangement, liability related to the sale of future royalties, valuation of stock-based awards and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates and could materially affect the reported amounts of assets, liabilities and future operating results.

***Liability Related to the Sale of Future Royalties***

In December 2023, the Company entered into a royalty interest financing agreement with United in Endeavor, or United, pursuant to which the Company sold to United an interest in royalty and milestone payments the Company receives based on net sales of XACIATO. The Company received $ 5.0 million from United in connection with entering into the royalty interest financing agreement. The Company evaluated the terms of the royalty interest financing agreement and concluded that its features were similar to those of a debt instrument. The Company recognized the $ 5.0 million it received as a liability on its consolidated balance sheet because the Company agreed to make payments to United until such time that United has received aggregate payments equaling a 12 % internal rate of return on the $ 5.0 million. Interest expense for the liability related to the sale of future royalties is recognized using the effective interest rate method over the expected term of the royalty interest financing agreement.

The liability related to the sale of future royalties and related interest expense are based on current estimates of future royalties, which estimates are based on forecasts of XACIATO net sales. The Company periodically assesses the forecasted net sales and to the extent the amount or timing of estimated royalty payments are materially different than previous estimates, the Company will account for any such change by adjusting the liability related to the sale of future royalties and prospectively recognizing the related non-cash interest expense.

In connection with the royalty investment financing agreement the Company entered into, the Company issued a warrant to purchase up to an aggregate of 5.0 million shares of the Company's common stock. The warrant was allocated a relative fair value of approximately $ 0.8 million using a Black-Scholes option pricing model. The $ 0.8 million relative fair value of the warrant was recorded as a debt discount with an offset to additional paid in capital on the 2023 consolidated balance sheet as the warrants were deemed to be equity classified.

***Risks and Uncertainties***

The Company will require approvals from the FDA, or foreign regulatory agencies prior to being able to sell any products. The Company received approval from the FDA for XACIATO in December 2021. 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, successfully commercialize approved products or enter into strategic relationships with third parties who are able to successfully commercialize approved products, raise additional capital, compete with other products, and protect proprietary technology. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company’s future success.

***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***

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.

The following tables present the classification within the fair value hierarchy of financial assets and liabilities that are remeasured on a recurring basis as of December 31, 2023 and December 31, 2022. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) as of December 31, 2023.

| | Fair Value Measurements | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Balance at December 31, 2023** | | | | |
| **Current assets:** | | | | |
| Cash equivalents [1] | $ 9,982,079 | $ — | $ — | $ 9,982,079 |
| **Balance at December 31, 2022** | | | | |
| **Current assets:** | | | | |
| Cash equivalents [1] | $ 33,238,658 | $ — | $ — | $ 33,238,658 |

[1] Represents cash held in money market funds.

***Revenue Recognition***

Under Accounting Standards Codification Topic 606, or ASC 606, the Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligations. At contract inception, the Company assesses the goods or services agreed upon within each contract, assesses whether each good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company develops estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

*Collaboration Revenues.* The Company enters into collaboration and licensing agreements under which it out-licenses certain rights to its products or product candidates to third parties. The terms of these arrangements typically include payment of one or more of the following to the Company: non-refundable, up-front license fees; development, regulatory and/or commercial milestone payments; and royalties on net sales of licensed products. To date, the Company has not recognized any collaboration revenues.

*License Fee Revenue.* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use

and benefit from the license. For licenses bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. To date, the Company has recognized $ 11.0 million in license fee revenue, $ 10.0 million of which represents the upfront payment under its license agreement for XACIATO and $ 1.0 million of which represents the payment required by the first amendment to such license agreement entered into in July 2023.

*Royalties.* For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has recognized approximately $ 7,900 in royalty revenue.

*Product Supply.* Arrangements that include a promise for future supply of product for commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company evaluates whether it is the principal or agent in the arrangement. The evaluation is based on the degree the Company controls the specified product at any time before transfer to the customer. Revenues are recognized on a gross basis if the Company is in the capacity of principal and on a net basis if the Company is in the capacity of an agent. To date, the Company has recognized approximately $ 205,000 in revenue along with $ 201,000 in other expense attributed to the cost of revenue associated with its product supply arrangement for XACIATO, which is recorded in other income in the Company's 2023 consolidated statement of operations and comprehensive loss. That arrangement was terminated effective December 14, 2023 and the Company will not recognize product supply revenue associated with that agreement in the future.

*Bayer License*. In 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. and received a $ 1.0 million upfront non-refundable license fee payment from Bayer (See Note 3, Strategic Agreements). The $ 1.0 million upfront payment is recorded as deferred license revenue in the Company's consolidated balance sheets at December 31, 2023 and December 31, 2022. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $ 20.0 million. The Company concluded that there was one significant performance obligation related to the $ 1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $ 20.0 million fee. The $ 1.0 million upfront payment will be recorded as license revenue at the earlier of (i) the point in time the Company receives the $ 20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (ii) the termination of the agreement. To date, neither of the foregoing has occurred.

Under its license agreement with Bayer, the Company will also be entitled to receive (a) milestone payments totaling up to $ 310.0 million related to the commercial sales of Ovaprene, 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.

*Milestone Payments.* At the inception of each arrangement in which the Company is a licensor and that includes developmental, regulatory or commercial milestones, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Potential future milestone payments not within the Company's control, such as where achievement of the specified milestone depends on activities of a third party or regulatory approval, are not considered probable of being achieved until the specified milestone occurs. As of December 31, 2023, the Company has recognized $ 1.8 million of milestone payment revenues.

Potential future payments for variable consideration, such as commercial milestones, will be recognized when it is probable that, if recorded, a significant reversal will not take place. Potential future royalty payments will be recorded as revenue when the associated sales occur (See Note 3, Strategic Agreements).

***Leases***

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

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date 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 also 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 10, Leased Properties).

***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 health.

***Australian Research and Development Tax Incentive Program***

The Company is eligible under the Australian Research and Development Tax Incentive Program, or the Tax Incentive, to receive a cash refund from the Australian Taxation Office for eligible research and development expenditures. To be eligible, the Company must have revenue of less than AUD $ 20.0 million during the reimbursable period and cannot be controlled by income tax exempt entities. Grants received by the Company that do not require the transfer of goods or services to a customer are accounted for by analogy to IAS 20. Under IAS 20, the Company recognizes the Tax Incentive as a reduction to research and development expense when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured. The Company classifies its estimate for the Tax Incentive as other current assets on its consolidated balance sheets. For the years ended December 31, 2023 and 2022, the Company recognized approximately $ 0.6 million and approximately $ 1.6 million, respectively, as a reduction to research and development expense for expenses incurred that it believes are eligible for the Tax Incentive. At December 31, 2023 and 2022, the Company recorded a receivable for the estimated Tax Incentive of approximately $ 0.6 million and $ 1.6 million, respectively, in other receivables on the accompanying consolidated balance sheets.

***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 contract 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, milestone payments incurred or probable to be incurred for the Company's in-licensing arrangements, 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.

***Patent Costs***

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the consolidated statements of operations.

***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 9,463,556 and 6,612,554 shares of common stock outstanding at December 31, 2023 and 2022, respectively. There were warrants exercisable into 15,006,500 and 1,381,015 shares

of common stock outstanding at December 31, 2023 and 2022, 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, the volatility of the Company's common stock, 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. The Company compared U.S. Treasury Bills in determining the risk-free interest rate appropriate given the expected term. The Company has not established and has no plans to establish, a dividend policy, and the Company has not declared, and has no plans to declare 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 FASB 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 each of December 31, 2023 and 2022, the Company did not record any liabilities for uncertain tax positions.

During each of 2023 and 2022, the Company recorded no provision for income taxes. Management evaluated the Company’s tax positions and, as of December 31, 2023 and 2022, the Company had approximately $ 2.6 million and $ 2.3 million of unrecognized benefits, respectively. The tax years 2020 to 2022 and 2019 to 2022 remain open to examination by federal and state taxing authorities, respectively, while the statute of limitations for U.S. net operating losses generated remain open beginning in the year of utilization.

***Indemnification Obligations***

As permitted under Delaware law, the Company has entered into indemnification agreements with its officers and directors that provide that the Company will indemnify its 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, 2023, 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, 2023 and 2022, no amounts have been accrued related to such indemnification provisions.

## 3. STRATEGIC AGREEMENTS

***Strategic Agreements for Product Commercialization***

**Organon Exclusive License Agreement**

In March 2022, the Company entered into an exclusive license agreement with Organon which became effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property controlled by the Company. In July 2022, the Company received a $ 10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue. In July 2023, the Company received a $ 1.0 million payment from Organon in connection with the amendment to the license agreement the parties entered into, which was also recorded as license fee revenue. In the fourth quarter of

2023, in connection with the first commercial sale in the U.S. of XACIATO in accordance with the license agreement, as amended, the Company received the $ 1.8 million milestone payment from Organon.

Under the terms of the license agreement, as amended, the Company is entitled to receive tiered double-digit royalties based on net sales and up to $ 180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets.

At the inception of the license agreement, the Company concluded that the transaction price was $ 10.0 million and should not include the variable consideration related to unachieved development, regulatory, commercial milestones and future sales-based royalty payments. This consideration was determined to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue. The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. For the year ended December 31, 2023, the transaction price was updated to $ 11.0 million.

The Company will recognize any consideration related to sales-based payments, including milestones and royalties which relate predominantly to the license granted, at the later of (i) when or as the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company was responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumed such responsibilities, which occurred in December 2023. Prior to that time, Organon purchased all of its product requirements of XACIATO from the Company at a transfer price equal to the Company's manufacturing costs plus a single-digit percentage markup.

Unless terminated earlier, the agreement will expire on a product-by-product and country-by-country basis upon expiration of the applicable royalty period for each licensed product. In addition to customary termination rights for both parties, following the first anniversary of the effective date of the agreement, Organon may terminate the agreement in its entirety or on a country-by-country basis at any time in Organon's sole discretion on 120 days' advance written notice.

**Bayer HealthCare License Agreement**

In January 2020, the Company entered into a license agreement with Bayer, regarding the further development and commercialization of Ovaprene in the U.S. The Company received a $ 1.0 million upfront non-refundable license fee payment from Bayer and Bayer agreed to support the Company in development and regulatory activities by providing the equivalent of two experts to advise the Company in clinical, regulatory, preclinical, commercial, CMC and product supply matters. The Company is responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $ 20.0 million, referred to as the $ 20 million fee. After payment of the $ 20 million fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S. Such license would be exclusive as to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with the Company with regard to development.

The Company concluded there was one significant performance obligation related to the $ 1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $ 20.0 million fee. The $ 1.0 million upfront payment will be recorded as license revenue at the earlier of (i) the point in time the Company receives the $ 20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (ii) the termination of the agreement. As of December 31, 2023, neither of the foregoing had occurred. The $ 1.0 million payment is recorded as long-term deferred license revenue in the Company's consolidated balance sheets at December 31, 2023 and 2022.

If Bayer elects to make the license effective, the Company 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.

The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S. or 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 the Company does not receive the $ 20.0 million fee if and when due.

***Strategic Agreements for Pipeline Development***

**Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement**

In August 2023, the Company entered into a license agreement with Douglas Pharmaceuticals Limited, or Douglas, under which the Company acquired the exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia (CIN) and other HPV-related pathologies, and an agreement with The University of Manchester, pursuant to which The University of Manchester consented to Douglas' sublicense to the Company of certain rights it previously granted to Douglas and agreed to grant the Company a direct license to such rights if its license agreement with Douglas is terminated. Under the Company's agreement with Douglas, it received an exclusive, royalty-bearing license to research, develop and commercialize the licensed intellectual property in the United States for the treatment or prevention of all indications for women in female reproductive health. The Company is entitled to sublicense the rights granted to it under the agreement.

Under the terms of the Douglas agreement, the Company agreed to make potential future payments of up to $ 5.25 million in the aggregate upon achievement of certain development and regulatory milestones, and of up to $ 64.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement. The development and regulatory milestones may be paid in shares of the Company’s common stock, in the Company's sole discretion subject to specified limitations. Additionally, Douglas is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on annual net sales of products and processes covered by the licenses granted under the agreement. As of December 31, 2023, no payments had been made under the Douglas agreement.

**Hennepin License Agreement**

In August 2022, the Company entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which the Company acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. Under the agreement, the Company received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. The Company is entitled to sublicense the rights granted to it under the agreement.

Under the terms of the license agreement, the Company agreed to make potential future payments of up to $ 6.25 million in the aggregate upon achievement of certain development and regulatory milestones, and up to $ 45.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement, which may be paid, in the Company’s sole discretion, in cash or shares of the Company’s common stock. Additionally, Hennepin is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement. As of December 31, 2023, no payments have been made under this agreement.

**MBI Acquisition**

In November 2019, the Company acquired Dare MB Inc., or MBI, to secure the rights to develop a long-acting reversible contraception method, that a woman can turn on or off herself, according to her own needs. This candidate is now known as DARE-LARC1.

Under the terms of the merger agreement, the Company agreed to pay former MBI stockholders: (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 the Company acquired in the merger; and (c) tiered royalty payments ranging from low single-digit to low double-digit percentages based on annual net sales of such products sold by the Company (but not by sublicensee) and a percentage of sublicense revenue related to such products.

In June 2021, a total of $ 1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events. In accordance with the terms of the merger agreement, the Company's board of directors elected to pay a portion of these milestone payments in shares of the Company's common stock, and in September 2021, the Company issued approximately 700,000 shares of its common stock to former stockholders of MBI and paid $ 75,000 in cash to the stockholders' representative in satisfaction of the $ 1.25 million in milestone payments associated with milestones achieved in June 2021.

**TriLogic and MilanaPharm License Agreement / Hammock Assignment Agreement**

In December 2018, the Company entered into an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and 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 XACIATO, this proprietary technology is formulated with clindamycin for the treatment of bacterial vaginosis. In December 2019, the Company entered into amendments to each of the Assignment Agreement and License Amendment. In September 2021, the Company entered into a second amendment to the License Agreement. In March 2022, the Company entered into a consent, waiver and stand-By license Agreement with TriLogic, MilanaPharm and Organon, which further amended the License Agreement.

Under the terms of the License Agreement, the Company paid clinical and regulatory development milestones of $ 300,000 in the aggregate to MilanaPharm, the final payment of which was made in 2021, and $ 500,000 in connection with the first commercial sale in the United States of XACIATO in the fourth quarter of 2023. Additionally, the Company may pay up to $ 250,000 upon the first commercial sale in the United States of successive licensed products for each vaginal or urological use. In addition, upon achievement of $ 50.0 million in cumulative worldwide net sales of licensed products the Company must pay MilanaPharm $ 1.0 million. MilanaPharm is also eligible to receive (a) 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, and (b) high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes.

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. Hammock is eligible to receive up to $ 1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $ 850,000 of which has been paid as of December 31, 2023.

**Pear Tree Acquisition**

In May 2018, the Company acquired Pear Tree Pharmaceuticals, Inc., or Pear Tree, to secure exclusive, sublicensable, worldwide rights under certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration. This acquisition led to the Company's DARE-VVA1 program.

Under the terms of the merger agreement, the Company agreed to pay the former stockholders of Pear Tree: (a) up to $ 15.5 million in the aggregate upon achievement of certain clinical development and regulatory milestones by licensed products, and (b) up to $ 47.0 million in the aggregate upon achievement of certain commercial milestones by licensed products. Additionally, the former stockholders of Pear Tree are eligible to receive tiered royalties based on single-digit to low double-digit percentages of annual net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, and a portion of royalties the Company receives from sublicensees. Both the milestone and royalty payments may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the merger agreement. Under the merger agreement, in addition to customary royalty reductions and offsets, royalty payments and payments based on income received from sublicensees of licensed products made by the Company to Pear Tree's licensors are creditable against all royalty and sublicense revenue share payments payable to the former stockholders of Pear Tree.

The Company agreed to pay licensors of Pear Tree (a) up to approximately $ 3.2 million in the aggregate upon achievement of certain clinical development, regulatory and commercial milestones by each licensed product, and (b) semi-annual royalties based on a single-digit percentage of net sales of licensed products by the Company or

its affiliates, subject to customary reductions and offsets, or a portion of any royalties the Company or its affiliates receives from sublicensees, and a low double-digit percentage of all sublicensing fees or other lump sum payments or compensation the Company receives from sublicensees, subject to customary exclusions. The milestone payments to the licensors of Pear Tree may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the license agreements. Portions of certain milestone payments made to Pear Tree's licensors may be creditable against royalty payments due to Pear Tree's licensors.

**Catalent JNP License Agreement**

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc., or 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.

Under the terms of the license agreement, the Company paid a $ 250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement and will pay a $ 100,000 annual license maintenance fee on each anniversary of the date of the agreement. The annual maintenance fee 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. Catalent is eligible to receive up to (a) $ 13.5 million in the aggregate in payments based on the achievement of specified development and regulatory milestones, $ 1.0 million of which has been paid as of December 31, 2023; and (b) up to $ 30.3 million in the aggregate in payments based on the achievement of specified commercial sales milestones for each product or process covered by the licenses granted under the agreement. Additionally, Catalent is eligible to receive 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.

**Adare Development and Option Agreement**

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharmaceuticals USA, Inc., or Adare, for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which the Company refers to as DARE-204 and DARE-214, respectively). The agreement, as amended, provides the Company with an option to negotiate an exclusive, worldwide, royalty-bearing license, with rights to sublicense, for the programs if the Company funds the conduct of specified development work. The Company has no obligation to exercise its option.

**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, including treatment of female sexual arousal disorder and/or female sexual interest/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 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, or the Licensed Products.

SST will be eligible to receive payments of up to $ 18.0 million in the aggregate upon achievement of certain clinical and regulatory milestones in the U.S. and worldwide, and up to $ 100.0 million in the aggregate upon achievement of 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. Additionally, SST

is eligible to receive tiered royalties based on percentages of annual net sales of licensed products in the single-digit to mid double-digits subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

**ADVA-Tec License Agreement**

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

Under the terms of the license agreement, the Company will pay ADVA-Tec (a) up to $ 14.6 million in the aggregate based on the achievement of specified development and regulatory milestones, $ 1.2 million of which has been paid; and (b) up to $ 20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones.

Additionally, ADVA-Tec is eligible to receive 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, subject to customary reductions and offsets.

If the Company sublicenses its rights under the agreement, in lieu of royalty payments to ADVA-Tec, ADVA-Tec is eligible to receive a double-digit percentage of sublicense revenue received by the Company during the royalty term; provided, however, that for sublicense revenue the Company receives prior to the first commercial sale of a licensed product that represents an upfront payment or license fee due on or around the effective date of the sublicense, ADVA-Tec is eligible to receive a single-digit percentage of that sublicense revenue.

## 4. PREPAID EXPENSES

Prepaid expenses consisted of the following:

| | As of December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Prepaid clinical expense | $ 5,023,140 | $ 5,702,657 |
| Prepaid development expense | 376,959 | 225,433 |
| Prepaid insurance expense | 472,922 | 502,981 |
| Prepaid legal and professional expenses | 245,251 | 234,917 |
| Total prepaid expenses | $ 6,118,272 | $ 6,665,988 |

## 5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

| | As of December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Accrued clinical expense | $ 1,195,744 | $ 6,665,443 |
| Accrued compensation and benefits | 805,412 | 1,720,501 |
| Accrued development expense | 547,490 | 2,102,310 |
| Accrued royalties payable | 6,504 | — |
| Accrued legal and professional | — | 239,348 |
| Insurance financing payable | 267,188 | — |
| Other accruals | — | 99,747 |
| Accrued license fee expense | 66,667 | 66,667 |
| Total accrued expenses | $ 2,889,005 | $ 10,894,016 |

## 6. VENDOR CONCENTRATION

The Company had one major vendor that accounted for approximately 21 % and 10 % of the Company's research and development expenditures for the years ended December 31, 2023 and 2022, respectively. The same vendor also accounted for approximately 0 % and 17 % of the Company's total accounts payable and accrued expenses as of December 31, 2023 and 2022, respectively. The Company continues to maintain its relationship with this vendor and anticipates incurring significant expenses with this vendor over the next 12 months.

## 7. INCOME TAXES

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

| | Years Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Domestic | $ 29,099 | $ 28,391 |
| Foreign | 1,060 | 2,557 |
| Loss before taxes | $ 30,159 | $ 30,948 |

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, 2023 and 2022 are as follows:

| | Years Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Federal statutory rate | 21.0 % | 21.0 % |
| State income tax, net of federal benefit | 0.84 % | ( 2.96 )% |
| State tax rate change | 1.15 % | ( 9.08 )% |
| Permanent differences | ( 0.02 )% | ( 0.02 )% |
| Research and development credit | 7.47 % | 6.84 % |
| Stock compensation | ( 0.75 )% | ( 0.57 )% |
| Other | ( 3.04 )% | ( 0.74 )% |
| Change in valuation allowance | ( 26.65 )% | ( 14.48 )% |
| Effective income tax rate | — % | — % |

The major components of the Company’s deferred tax assets as of December 31, 2023 and 2022 are shown below (in thousands).

| | 2023 | 2022 |
|---|---|---|
| Net operating loss carryforwards | $ 86,182 | $ 81,761 |
| Research and development credit carryforwards | 10,868 | 8,833 |
| Capitalized research and development costs | 12,570 | 10,009 |
| Other | 41 | 1,468 |
| Stock compensation | 2,618 | 2,170 |
| Total deferred tax assets | 112,279 | 104,241 |
| Valuation allowance | ( 112,279 ) | ( 104,241 ) |
| 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 $ 112.3 million and $ 104.2 million was established at December 31, 2023 and 2022, 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 $ 8.0 million and $ 4.5 million for the years ending December 31, 2023 and 2022, respectively, 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, 2023 of approximately $ 314.9 million of which $ 1.2 million begin expiring in 2024 unless previously utilized and $ 117.7 million that do not expire. The Company has state NOL carryforwards of $ 294.1 million that begin expiring in 2031 unless previously utilized. The Company has U.S. federal research credit carryforwards available at December 31, 2023 of approximately $ 10.4 million that begin expiring in 2027 unless previously utilized. The Company has state research credit carryforwards of $ 2.7 million of which $ 0.2 million begin expiring in 2024 unless previously utilized. These federal and state research and development credits are subject to a 20% reserve under FASB ASC 740. 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.

A reconciliation of the beginning and ending amount of uncertain tax benefits is as follows (in thousands):

| | Years Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Beginning uncertain tax benefits | $ 2,316 | $ 1,909 |
| Current year - increases | $ 347 | $ 427 |
| Prior year - reductions | $ ( 46 ) | $ ( 20 ) |
| Ending uncertain tax benefits | $ 2,617 | $ 2,316 |

Included in the balance of uncertain tax benefits at December 31, 2023 are $ 2.6 million of tax benefits that, if recognized, would result in a reduction of the gross deferred tax asset, offset fully by valuation allowance and have no net impact on the financial statements. 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, 2023 and 2022, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The tax years 2019 through 2023 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, 2023.

## 8. STOCKHOLDERS' EQUITY

***Increase in Authorized Shares of Common Stock***

In July 2022, following the approval of the Company's stockholders at its annual meeting of stockholders, the Company amended its restated certificate of incorporation to increase the Company's authorized shares of common stock to 240.0 million.

***September 2023 Registered Direct Offering***

In August 2023, the Company entered into a securities purchase agreement with an institutional investor and an investor affiliated with Douglas for the purchase and sale of 10,000,000 shares of the Company's common stock and warrants to purchase an aggregate of 10,000,000 shares of the Company's common stock in a registered direct offering priced at-the-market under Nasdaq rules. The offering closed on September 1, 2023. Each warrant is exercisable for one share of the Company's common stock. The terms of the warrants are further described below in this Note 8. The offering price was $ 0.70 per share of common stock and accompanying warrant. The aggregate gross proceeds to the Company from the offering were $ 7.0 million, and net proceeds were approximately $ 7.0 million. The offering was made pursuant to the Company's registration statement on Form S-3 (File No. 333-254862), filed with the SEC on March 30, 2021, and declared effective by the SEC on April 7, 2021, and a prospectus supplement thereunder.

***March 2023 ATM Sales Agreement***

In March 2023, the Company entered into a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, and Cantor Fitzgerald & Co., or Cantor, to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program under which Stifel and Cantor act as the Company's agents. The Company agreed to pay a commission equal to 3 % of the gross proceeds of any common stock sold under the agreement or such lower amount as the Company and Stifel and Cantor agree, plus certain legal expenses. Shares of the Company's common stock sold under the agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-254862), the base prospectus included therein, originally filed with the SEC on March 30, 2021 and declared effective by the SEC on April 7, 2021, the prospectus supplement dated March 31, 2023 relating to the offering of up to $ 50.0 million of shares of the Company's common stock under the sales agreement, and any subsequent prospectus supplement related to the offering of shares of the Company's common stock under the sales agreement. During the year ended December 31, 2023, the Company sold 3,794,936 shares of common stock under this agreement and received aggregate gross proceeds of approximately $ 2.4 million and incurred sales agent commissions and fees of approximately $ 55,000 .

***October 2021 ATM Sales Agreement***

In October 2021, the Company entered into a sales agreement with SVB Securities LLC (formerly known as SVB Leerink LLC) to sell shares of its common stock from time to time through an ATM equity offering program under which SVB Securities acted as the Company's agent. The Company sold no shares of its common stock under the agreement during year ended December 31, 2023. During the year ended December 31, 2022, the Company sold 751,040 shares of its common stock under the agreement for gross proceeds of approximately $ 1.3 million and incurred offering expenses of approximately $ 42,000 . The Company terminated the agreement in March 2023.

***Common Stock Warrants***

**December 2023 Warrants**

In connection with the royalty interest financing agreement the Company entered into in December 2023, the Company issued a warrant to purchase up to an aggregate of 5,000,000 shares of the Company's common stock. The warrant has a term of five years from the date of issuance and an exercise price of $ 0.3467 per share, subject to customary adjustment for stock splits and similar transactions. A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99 % (or, at the election of the holder 9.99 %) of the Company's outstanding common stock immediately after exercise. The warrant includes certain rights in favor of the holder upon a “fundamental transaction” as described in the warrant, including the right of the holder to receive from the Company or the successor entity an amount of cash equal to the Black-Scholes value (as described in the warrants) of the unexercised portion of the warrant on the date of the consummation of such fundamental transaction.

The warrant was allocated a value of $ 0.8 million using a Black-Scholes option pricing model based on the relative fair value method as they were issued with common stock. The Black-Scholes model used the following assumptions: expected volatility: 85.91 %; risk-free interest rate: 4.05 %; expected dividend yield: 0 %; and expected term: 5 years. The warrant was deemed to be classified as equity and recorded within additional paid in capital on the 2023 consolidated balance sheet. As of December 31, 2023, no portion of the warrant has been exercised.

**September 2023 Warrants**

In connection with the registered direct offering completed in September 2023, the Company issued warrants to purchase up to an aggregate of 10,000,000 shares of the Company's common stock. The warrants became exercisable on March 1, 2024, expire March 1, 2029 and have an exercise price of $ 0.77 per share, subject to customary adjustment for stock splits and similar transactions. A holder (together with its affiliates) may not exercise any portion of a warrant to the extent that the holder would own more than 4.99 % (or, at the election of the holder 9.99 %) of the Company's outstanding common stock immediately after exercise. The warrants include certain rights in favor of the holders upon a “fundamental transaction” as described in the warrants, including the right of the holders to receive from the Company or the successor entity an amount of cash equal to the Black-Scholes value (as described in the warrants) of the unexercised portion of the warrants on the date of the consummation of such fundamental transaction.

The warrants were allocated a value of $ 2.9 million using a Black-Scholes option pricing model based on the relative fair value method as they were issued with common stock. The Black-Scholes model used the following assumptions: expected volatility: 87.77 %; risk-free interest rate: 4.29 %; expected dividend yield: 0 %; and expected term: 5.5 years. The warrants were deemed to be classified as equity and recorded within additional paid in capital on the 2023 consolidated balance sheet. As of December 31, 2023, none of the warrants have been exercised.

**February 2018 Warrants**

In connection with an underwritten public offering in February 2018, the Company issued to the investors in that offering, warrants exercisable through February 15, 2023 with an initial exercise price of $ 3.00 per share. The Company estimated the fair value of the warrants as of February 15, 2018 to be approximately $ 3.0 million which was recorded in equity as of the grant date. The warrants included a price-based anti-dilution provision, which resulted in automatic reductions to the exercise price of the warrants in April 2019 and July 2020 to $ 0.98 per share and to $ 0.96 per share, respectively.

A summary of warrant activity during the years ended December 31, 2023 and 2022 is presented below:

| | Common Stock | | | |
|---|---|---|---|---|
| | Number of Shares Underlying Warrants | Weighted Average Exercise Price | Weighted Average Remaining Life in Years | Intrinsic Value |
| Outstanding, December 31, 2021 | 1,381,015 | $ 1.00 | | |
| Granted | — | — | | |
| Exercised | — | — | | |
| Forfeited or expired | — | — | | |
| Outstanding, December 31, 2022 | 1,381,015 | $ 1.00 | 0.23 | $ — |
| Granted | 15,000,000 | 0.63 | | |
| Exercised | ( 1,353,515 ) | ( 0.96 ) | | |
| Forfeited or expired | ( 21,000 ) | ( 0.96 ) | | |
| Outstanding and exercisable, December 31, 2023 | 15,006,500 | $ 0.63 | 5.11 | $ — |

***Common Stock***

The authorized capital of the Company consists of 240,000,000 shares of common stock with a par value of $ 0.0001 per share and 5,000,000 shares of preferred stock with a par value of $ 0.01 per share. The issued and outstanding common stock of the Company consisted of 99,973,932 and 84,825,481 shares of common stock as of December 31, 2023 and 2022, respectively. There were no shares of preferred stock outstanding as of December 31, 2023 or 2022.

*Common Stock Reserved for Future Issuance*

The following table summarizes common stock reserved for future issuance at December 31, 2023:

| | |
|---|---|
| Common stock reserved for issuance upon exercise of warrants outstanding | 15,006,500 |
| Common stock reserved for issuance upon exercise of options outstanding | 9,463,556 |
| Common stock reserved for future equity awards | 6,725,579 |
| Total | 31,195,635 |

**9. STOCK-BASED COMPENSATION**

***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, 2023 or December 31, 2022.

***Amended and Restated 2014 Stock Incentive Plan***

The Amended and Restated 2014 Stock Incentive Plan, or the Amended 2014 Plan, provided for the grant of stock-based awards to employees, directors, consultants and advisors. 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 increased annually on the first day of each fiscal year 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. On January 1, 2022, the number of available shares increased by 2,000,000 to 2,201,855 . As a result of the approval of the 2022 Plan (as defined below) by the Company's stockholders on June 23, 2022, no further awards have been or will be granted under the Amended 2014 Plan. Outstanding awards previously granted under the Amended 2014 Plan continue to remain outstanding in accordance with their terms.

***2022 Stock Incentive Plan***

In April 2022, the Company's board of directors approved the Daré Bioscience, Inc. 2022 Stock Incentive Plan, or the 2022 Plan, which was subsequently approved by the Company's stockholders on June 23, 2022, and

became effective as of that date. The 2022 Plan provides for the grant of stock-based incentive awards to employees, directors, consultants, and advisors.

The number of shares of common stock authorized for issuance under the 2022 Plan is (a) 10,117,305 ; plus (b) up to 6,144,682 shares subject to awards granted under the Amended 2014 Plan or the 2007 Stock Incentive Plan that expire, terminate or are otherwise forfeited on or after June 23, 2022.

***Summary of Stock Option Activity***

The table below summarizes stock option activity under the Company's stock incentive plans and related information for the years ended December 31, 2023 and 2022. The exercise price of all options granted during the years ended December 31, 2023 and 2022 was equal to the market value of the Company's common stock on the date of grant. As of December 31, 2023, unamortized stock-based compensation expense of approximately $ 4.3 million will be amortized over the weighted average period of 2.1 years. The number of shares of common stock available for future awards granted under the 2022 Plan as of December 31, 2023 was 6,725,579 .

| | Number of Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2021 | 4,717,602 | $ 1.65 | | |
| Granted | 2,346,692 | 1.50 | | |
| Exercised | ( 130,322 ) | 0.96 | | |
| Cancelled/forfeited | ( 321,418 ) | 1.94 | | |
| Expired | — | — | | |
| Outstanding at December 31, 2022 | 6,612,554 | 1.60 | | |
| Granted | 2,857,665 | 1.13 | | |
| Exercised | — | — | | |
| Canceled/forfeited | ( 6,663 ) | 1.17 | | |
| Expired | — | — | | |
| Outstanding at December 31, 2023 | 9,463,556 | $ 1.46 | 7.51 | $ — |
| Options exercisable at December 31, 2023 | 5,634,731 | $ 1.51 | 6.78 | $ — |
| Options vested and expected to vest at December 31, 2023 | 9,463,556 | $ 1.46 | 7.51 | $ — |

***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, | |
|---|---|---|
| | 2023 | 2022 |
| Research and development | $ 823,148 | $ 676,645 |
| General and administrative | 1,707,536 | 1,481,866 |
| Total | $ 2,530,684 | $ 2,158,511 |

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, 2023 and 2022 is as follows:

| | 2023 | 2022 |
|---|---|---|
| Expected life in years | 6.0 | 6.0 |
| Risk-free interest rate | 3.56 % | 2.00 % |
| Expected volatility | 107 % | 121 % |
| Dividend yield | 0.0 % | 0.0 % |
| Weighted-average fair value of options granted | $ 1.13 | $ 1.30 |

**10. LEASED PROPERTIES**

The Company's lease for its corporate headquarters ( 3,169 square feet of office space) commenced on July 1, 2018. In February 2022, the Company entered into an amendment to extend the term of the lease for two years such that the term now expires on August 31, 2024.

MBI, a wholly-owned subsidiary the Company acquired in November 2019, leases general office and laboratory space in Lexington, Massachusetts. The lease for that space commenced on July 1, 2013. In February 2022, the Company entered into an amendment to extend the term of the lease for three years to December 31, 2025, subject to the landlord's right to terminate the lease on December 31, 2023. The extension of the lease in February 2022 resulted in an increase in operating lease liabilities and ROU assets of approximately $ 1.0 million. In September 2022, the landlord exercised its option to terminate the lease, resulting in the new lease term ending on December 31, 2023. The termination of the lease resulted in a reduction of operating lease liabilities and ROU assets of approximately $ 0.5 million and $ 0.5 million, respectively, and a $ 46,000 gain on the modification of the lease which was included as a reduction to research and development expense for the year ended December 31, 2022. MBI entered into a new lease for general office space and laboratory space in June 2023 that commenced on November 1, 2023 for three years , expiring on December 31, 2026, and resulted in an increase in operating lease liabilities and ROU assets of approximately $ 1.3 million.

MBI previously leased warehouse space in Billerica, Massachusetts, under a lease that commenced on October 1, 2016 and terminated on March 31, 2022.

Under the terms of each lease, the lessee 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 uses an incremental borrowing rate consisting of the current prime rate plus 200 basis points for operating leases. The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At December 31, 2023, the Company reported operating lease ROU assets of approximately $ 1.3 million in other non-current assets, approximately $ 0.5 million in current portion of lease liabilities, and approximately $ 0.9 million in lease liabilities long-term in the consolidated balance sheets.

Total operating lease costs were approximately $ 0.6 million and $ 0.6 million for the years ended December 31, 2023 and 2022, respectively. 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 statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $ 0.4 million and $ 0.3 million for the years ended December 31, 2023 and 2022, respectively, and these amounts are included in operating activities in the consolidated statements of cash flows. At December 31, 2023, operating leases had a weighted average remaining lease term of 1.83 years and a weighted average interest rate of 10.27 %.

At December 31, 2023, future minimum lease payments under the Company's operating leases are as follows:

| Year ending December 31, | |
|---|---|
| 2024 | $ 592,000 |
| 2025 | 513,000 |
| 2026 | 529,000 |
| **Total future minimum lease payments** | 1,634,000 |
| Less: accreted interest | 229,000 |
| **Total operating lease liabilities** | $ 1,405,000 |

**11. SALE OF FUTURE ROYALTIES**

On December 21, 2023, the Company entered into a royalty interest financing agreement, or the Royalty Agreement, with United in Endeavour, LLC, or United, under which United acquired a portion of the Company's royalty interest in XACIATO. The Company received $ 5.0 million from United when the parties entered into the Royalty Agreement (the "Initial Investment"), and between January 1, 2024 and December 31, 2026, the Company may, in its sole discretion, elect to receive three additional payments (each a "Supplemental Investment") from United of up to an aggregate of $ 7.0 million, for a total of up to $ 12.0 million.

Under the Royalty Agreement, the Company agreed to make the following payments to United, until such time when United has received aggregate payments equaling a 12 % internal rate of return (the “IRR”) on the Initial Investment and each Supplemental Investment, if any (the "Hard Cap"): (i) from December 21, 2023 through December 31, 2025, 50 % of the amount of royalty payments remaining after all amounts that are due and payable and actually paid by the Company to any licensor or sublicensee on the royalty payments generated and received by the Company on net sales of XACIATO by Organon have been deducted (the “Net Royalty Payments”), (ii) from January 1, 2026 through December 31, 2029, 75 % of the Net Royalty Payments, and (iii) from December 21, 2023 through December 31, 2029, 10 % of the amount of milestone payments remaining after all amounts that are due and payable and actually paid by the Company to any licensor or sublicensee on the milestone payments generated and received by the Company on net sales of XACIATO by Organon have been deducted. After December 31, 2029, the Company will be required to make certain additional payments to United to the extent United has not received payments equaling the Hard Cap by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if United has not received payments equaling the Hard Cap by December 31, 2035 and the Company has other sources of assets or income besides XACIATO sufficient to complete such payments, the Company has agreed to pay United quarterly payments evenly divided over a two-year term, such that United will have obtained the IRR, taking into account all other payments received by United from the Company under the Royalty Agreement. United’s right to receive payments will terminate when United has received the Hard Cap.

The Company evaluated the terms of the Royalty Agreement and concluded that the features of the Royalty Agreement were similar to those of a debt instrument. As a result, the Company applied the debt recognition guidance under ASC 470, Debt, and recorded the Initial Investment as a liability related to the sale of future royalties (“Royalty Obligation”) on the Company's 2023 consolidated balance sheet, which will be amortized under the effective interest method over the estimated term of the Royalty Agreement. If the Company elects to receive additional Supplemental Investments, such additional Supplemental Investments will also be recorded as a liability related to the sale of future royalties when they are received and amortized under the interest method over the estimated remaining term of the Royalty Agreement. In addition, in accordance with ASC 470, Debt, the Company will account for any royalties received in the future as non-cash royalty revenue in the consolidated statements of operations as a reduction to the debt balance.

As royalties and milestone payments are received by the Company from Organon and the Company subsequently pays the amounts due to United in respect thereof in accordance with the Royalty Agreement, the Royalty Obligation will be effectively repaid during the term of the Royalty Agreement. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future payments to United during the term of the Royalty Agreement.

At execution of the Royalty Agreement, the Company’s estimate of this total interest expense resulted in an effective annual interest rate of approximately 22.48 %. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the royalty period. The Company will periodically assess the estimated amounts due and payable to United and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect XACIATO's commercial success, and therefore the amount and timing of the Company's payments to United, and correspondingly, the amount of interest expense recorded by the Company, most of which are not within the Company’s control. Such factors include, but are not limited to, the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product; timely and adequate commercial supply of the finished product and its components; perceived superiority of its cure rates compared to other available treatments; patient satisfaction and willingness to use it again and refer it to others; price pressure given the high level of generic treatments and changes in health care laws and regulations; adequate coverage, pricing and reimbursement from

third-party payors; and approval of new entrants, including alternative, non-antibiotic treatment options. These factors could result in increases or decreases to both royalty revenues and interest expense.

***Warrants***

In connection with entering into the Royalty Agreement, the Company issued to United a warrant (the "Initial Royalty Warrant") to purchase up to 5,000,000 shares of the Company's common stock. In addition, for every $ 1,000,000 of Supplemental Investment, the Company will issue a warrant to purchase 1,000,000 shares of common stock, for an aggregate of warrants to purchase up to 7,000,000 shares of common stock (collectively the "Additional Royalty Warrants," and together with the Initial Royalty Warrant, the "Royalty Agreement Warrants").

The Royalty Agreement Warrants are exercisable, in full or in part, at any time on or prior to the fifth anniversary of their issuance date at an exercise price of $ 0.3467 per share, subject to customary anti-dilution adjustments. The Royalty Agreement Warrants may be exercised for cash, or if at the time of exercise there is no effective registration statement registering for resale the shares underlying the Royalty Agreement Warrants, then in lieu of paying the exercise price in cash, the holders may elect to exercise on a cashless basis.

The Royalty Agreement Warrants were deemed to be equity classified warrants and recorded under additional paid in capital. The fair value of the Initial Royalty Warrant was determined to be $ 0.8 million (Note 8) and was recorded as a debt discount against the Initial Investment.

The following table shows the activity of the Royalty Obligation since the transaction inception through the period indicated:

| | December 31, 2023 | |
|---|---|---|
| Upfront payment from the sale of future royalties | $ | 5,000,000 |
| Debt issuance cost | | ( 276,101 ) |
| Relative fair value of Initial Royalty Warrant | | ( 834,512 ) |
| Royalty payments | | — |
| Non-cash interest expense associated with the sale of future royalties | | 24,289 |
| Liability related to the sale of future royalties | $ | 3,913,676 |

**12. COMMITMENTS AND CONTINGENCIES**

***Insurance Financing***

In July 2023, the Company obtained financing for director and officer and other insurance premiums. The agreement for such financing assigns to the lender a first priority lien on and a security interest in the financed insurance policies and any additional premium required in the financed insurance policies including (a) all returned or unearned premiums, (b) all additional cash contributions or collateral amounts assessed by the insurance companies in relation to the financed insurance policies and financed by the lender, (c) any credits generated by the financed insurance policies, (d) dividend payments, and (e) loss payments which reduce unearned premiums. If any circumstances exist in which premiums related to any financed insurance policy could become fully earned in the event of loss, the lender will be named a loss-payee with respect to such policy.

The total premiums, taxes and fees financed was approximately $ 0.6 million with an annual interest rate of approximately 8.0 %. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company promised to pay the lender the amount financed plus interest and other charges permitted under the agreement. The Company will make monthly installment payments on the financed amount through April 20, 2024. The financed amount is recognized as an insurance financing cost included in other current assets and accrued expenses in the Company's consolidated balance sheets. As of December 31, 2023, the Company's remaining obligation under the agreement was approximately $ 0.3 million.

***CRADA with NICHD for the Pivotal Phase 3 Study of Ovaprene***

In July 2021, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene, or the Ovaprene Phase 3. The Ovaprene Phase 3 will be conducted within NICHD's Contraceptive Clinical Trial Network with NICHD's contract research organization providing clinical coordination and data collection and management services for the Ovaprene Phase 3. The Company and NICHD will each provide medical oversight and final data review and analysis for the Ovaprene Phase 3 and will work

together to prepare the final report of the results of the Ovaprene Phase 3. The Company is responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $ 5.5 million in payments to NICHD to be applied toward the costs of conducting the Ovaprene Phase 3. NICHD is responsible for the other costs related to the conduct of the Ovaprene Phase 3. In accordance with the payment schedule under the CRADA, the Company has made aggregate payments of $ 5.0 million to NICHD, $ 3.5 million of which was paid in 2022. The Company's remaining obligation under the CRADA at December 31, 2023 is $ 0.5 million.

***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 of the Company are entitled to payments if their employment is terminated by the Company without cause, if they resign for good reason, if their employment agreements are not renewed, or if their employment is terminated by the Company without cause or if they resign for good reason, in each case, within three months prior to or 12 months following a change in control of the Company. Upon termination by the Company without cause, if they resign for good reason, if their employment agreements are not renewed, such executives are entitled to receive a payment of an amount equal to either nine or twelve months of base salary and to receive continuing health benefits coverage for periods equal to either nine or twelve months following the termination of employment or until such officer is covered under a separate plan from another employer. If their employment is terminated by the Company without cause or if they resign for good reason, in each case, within three months prior to or 12 months following a change in control of the Company, such executives will be entitled to receive a payment of an amount equal to either twelve or eighteen months of base salary and target bonus and to receive continuing health benefits coverage for periods ranging between twelve and 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.

***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 $ 213,000 and $ 200,000 during the years ended December 31, 2023 and 2022, respectively.

## 13. GRANT AWARDS

***NICHD Non-Dilutive Grant Funding***

The Company has received notices of awards and non-dilutive grant funding from NICHD to support the development of several of its product candidates. NICHD 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 statements of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

**DARE-PTB1**

In August 2020, the Company received a notice of award of a grant from NICHD to support the development of DARE-PTB1. The award of approximately $ 300,000 was to be used for what is referred to as the "Phase I" segment of the project outlined in the Company's grant application. The Phase I segment ended in July 2023. The Company recorded credits to research and development expense for costs related to the NICHD award of approximately $ 1,000 and $ 20,000 for the year ended December 31, 2023 and 2022. The Company received aggregate reimbursements under the award of approximately $ 216,000 during the grant period which ended in July 2023. No further funds are available under this award for the Phase I segment.

In December 2023, the Company received a notice of award of approximately $ 2.0 million for the "Phase II" segment of the project. The Company recorded no credits to research and development expense for costs related to the NICHD award for the year ended December 31, 2023.

**DARE-LARC1**

In September 2021, the Company received a notice of award of a grant from NICHD to support the development of DARE-LARC1. The award in the amount of approximately $ 300,000 is to be used to explore device insertion and removal in nonclinical studies.

The Company recorded credits to research and development expense of approximately $ 32,000 and $ 239,000 for costs related to the NICHD award for the year ended December 31, 2023 and 2022, respectively. The Company recorded receivables of approximately $ 0 and $ 33,000 for expenses incurred through such date that it believes is eligible for reimbursement under the grant at December 31, 2023 and 2022, respectively. The Company received aggregate reimbursements under the NICHD award of approximately $ 278,000 during the grant period, which ended in June 2023. No further funds are available under this award.

**DARE-204 and DARE-214**

In May 2022, the Company received a notice of award of a grant from NICHD of approximately $ 249,000 to support end-user research to better understand women's preferences for a long-acting injectable contraceptive method. The findings from the research will inform the Company's target product profile and guide its development priorities for DARE-204 and DARE-214.

The Company recorded credits to research and development expense of approximately $ 134,000 and $ 116,000 for costs related to the NICHD award for the year ended December 31, 2023 and 2022. The Company received aggregate reimbursements under the NICHD award of approximately $ 249,000 during the grant period, which ended in September 2023. No further funds are available under this award.

**DARE-PTB2**

In July 2023, the Company received a notice of award of a grant from NICHD of approximately $ 385,000 to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds will support activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida, which are to occur over a 12-month period.

The Company recorded credits to research and development expense of approximately $ 100,000 for costs related to the NICHD award for the year ended December 31, 2023. The Company recorded a receivable of approximately $ 100,000 at December 31, 2023 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

***Other Non-Dilutive Grant Funding***

The Company has received funding to support the preclinical development of DARE-LARC1 and DARE-LBT under grant agreements it entered into with the Foundation in June 2021 and November 2022, respectively. The Company is required to apply the funds it receives under the agreements solely toward direct costs for the applicable funded projects, other than approximately 10% of such funds, which it may apply toward general overhead and administrative expenses that support the entire operations of the Company. The Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Funds received that have not been spent are recorded as cash and cash equivalents and as a deferred grant funding liability in the Company’s consolidated balance sheets. The deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. The grant agreements include the Foundation's standard discretionary termination provisions. Any grant funds that have not been used or committed to the funded project must be returned promptly to the Foundation upon expiration or termination of the agreement.

**2021 DARE-LARC1 Grant Agreement**

In June 2021, the Company entered into an agreement with the Foundation under which the Company was awarded up to approximately $ 49.0 million to support the development of DARE-LARC1. The agreement supports technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 through nonclinical proof-of-principle studies and other IND-enabling work to allow for the submission of an IND application with the FDA, approval of which will be required to commence testing in humans.

As of December 31, 2023, the Company has received a cumulative total of approximately $ 28.4 million in non-dilutive funding under the agreement: approximately $ 11.5 million in 2021, approximately $ 12.4 million in 2022,

and $ 4.5 million in 2023. Additional payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones. The Company recorded credits to research and development expense of approximately $ 8.7 million and $ 5.2 million for costs related to the Foundation award for the year ended December 31, 2023 and 2022. As of December 31, 2023, the Company recorded a deferred grant funding liability of approximately $ 13.5 million in the Company's consolidated balance sheets.

**2022 DARE-LBT Grant Agreement**

In November 2022, the Company entered into an agreement with the Foundation under which the Company was awarded $ 585,000 to support the development of DARE-LBT over the period of November 11, 2022 to February 29, 2024. Under the agreement, the Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Any unspent funds are recorded as a deferred grant funding liability in the Company's consolidated balance sheets.

The Company received the full amount of the award in November 2022. The Company recorded credits to research and development expense of approximately $ 0.3 million and $ 12,000 for costs related to the Foundation award for the year ended December 31, 2023 and 2022. As of December 31, 2023, the Company has recorded approximately $ 246,000 of deferred grant funding in the Company's consolidated balance sheets.

## 14. SUBSEQUENT EVENTS

***Leased Property***

On March 8, 2024, the Company entered into an amendment to extend the term of the lease for its corporate headquarters in San Diego, California for three years . The extended term begins September 1, 2024 and expires October 31, 2027.

**2024 Biotherapeutic Product Grant Agreement**

On January 17, 2024, the Company entered into an agreement with the Foundation under which the Company was awarded $ 750,000 to support the development of bacteria-based live biotherapeutic products designed to benefit women and newborns. The Company received the full amount of the award in January 2024. The Company will track and report eligible expenses incurred to the Foundation. Funds received but not yet spent will be recorded as cash and cash equivalents and as a deferred grant funding liability in the Company's consolidated balance sheets.

***Related Party Transaction***

On January 26, 2024, the Company entered into a consulting agreement with its former Chief Financial Officer, Lisa Walters-Hoffert, to assist in transition matters subsequent to her retirement. Pursuant to the agreement, for a nine month period commencing on January 26, 2024, the Company will pay Ms. Walters-Hoffert $ 31,667 per month and up to $ 500 per month for her health insurance premiums.

***ATM Sales***

During January 2024, the Company sold an aggregate of 607,968 shares of common stock under its ATM equity offering program and received aggregate gross proceeds of approximately $ 220,000 and incurred sales agent commissions and fees of approximately $ 5,000 . For a discussion of the ATM program, see Note 8, Stockholders' Equity.

**EXHIBIT 4.4**

**Form of Warrant**

**DARÉ BIOSCIENCE, INC.**

**Warrant To Purchase Common Stock**

Warrant No.: [ ]
Date of Issuance: [ ] (" **Issuance Date**")

THIS COMMON STOCK PURCHASE WARRANT (the " Warrant") certifies that, for value received, _____ or its assigns (the " Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after [ ][1] (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on [ ][2] (the "Termination Date ") but not thereafter, to subscribe for and purchase from Daré Bioscience, Inc., a Delaware corporation (the "Company"), up to [ ][3] shares (as subject to adjustment hereunder, the " Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Royalty Interest Financing Agreement, dated as of [ ] (the "Effective Date") between the Company and United in Endeavour, LLC, a limited liability company organized under the laws of the State of Georgia (the "Agreement").

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain

[1] In the case of the initial warrant, to be the Effective Date as defined in the Agreement. In the case of subsequent warrants, if any, to be the date on which Supplemental Discretionary Investment Amount 1, Supplemental Discretionary Investment Amount 2 or Supplemental Discretionary Investment Amount 3, as applicable, is made by UiE to the Company.

[2] In the case of the initial warrant, to be the date five years from the Effective Date. In the case of subsequent warrants, if any, to be five years from the date on which Supplemental Discretionary Investment Amount 1, Supplemental Discretionary Investment Amount 2 or Supplemental Discretionary Investment Amount 3, as applicable, is made by UiE to the Company.

[3] The number of share for the initial warrant will be 5,000,000, assuming an initial upfront payment of $5M. The number of shares issuable for each Supplemental Discretionary Investment Amount payment will be 1,000,000 shares (as adjusted consistent with Section 3(a) below) for each $1M paid by UiE to the Company.

records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be [$ ] [4], subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the Nasdaq Capital Market (the "Principal Market") as reported by Bloomberg L.P. (" Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

For purposes of Rule 144(d) promulgated under the 1933 Act, as in effect on the Effective Date, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued pursuant to the Agreement.

"Bid Price" means, as applicable: (i) the Closing Sale Price of the Common Stock on the Trading Day immediately preceding the date of the applicable Exercise Notice if such Exercise Notice is (1) both executed and delivered pursuant to Section 1(a) hereof on a day that is not a

[4] To be 110% of the closing sale price on the Effective Date.

Trading Day or (2) both executed and delivered pursuant to Section 1(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) the Bid Price of the Common Stock as of the time of the Holder's execution of the applicable Exercise Notice if such Exercise Notice is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 1(a) hereof, or (iii) the Closing Sale Price of the Common Stock on the date of the applicable Exercise Notice if the date of such Exercise Notice is a Trading Day and such Exercise Notice is both executed and delivered pursuant to Section 1(a) hereof after the close of "regular trading hours" on such Trading Day.

"Trading Day" means, as applicable, (x) with respect to all price or trading volume determinations relating to the Common Stock, any day on which the Common Stock is traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded, provided that "Trading Day" shall not include any day on which the Common Stock is scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock is suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time) unless such day is otherwise designated as a Trading Day in writing by the Holder or (y) with respect to all determinations other than price or trading volume determinations relating to the Common Stock, any day on which The New York Stock Exchange (or any successor thereto) is open for trading of securities

"VWAP" means, for any security as of any date, the dollar volume-weighted average price for such security on the Principal Market (or, if the Principal Market is not the principal trading market for such security, then on the principal securities exchange or securities market on which such security is then traded) during the period beginning at 9:30:01 a.m., New York time, and ending at 4:00:00 p.m., New York time, as reported by Bloomberg through its "HP" function (set to weighted average) or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30:01 a.m., New York time, and ending at 4:00:00 p.m., New York time, as reported by Bloomberg, or, if no dollar volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in the "pink sheets" by OTC Markets Group Inc. (formerly Pink Sheets LLC). If the VWAP cannot be calculated for such security on such date on any of the foregoing bases, the VWAP of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination, recapitalization or other similar transaction during such period.

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise . The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless

exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise . If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise . In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common

Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii)

exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the U.S. Securities and Exchange Commission (the "Commission"), as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant. "Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with, such Person, it being understood for purposes of this definition that "control" of a Person means the power directly or indirectly either to vote 10% or more of the stock having ordinary voting power for the election of directors of such Person or direct or cause the direction of the management and policies of such Person whether by contract or otherwise. "Person" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity or a government or any department or agency thereof.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a

result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of

capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public

information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the original Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the " Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash . This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant . The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft,

destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Agreement.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

**********

*(Signature Page Follows)*

**IN WITNESS WHEREOF,** the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

**DARE BIOSCIENCE, INC.**

By: _____

**NOTICE OF EXERCISE**

To: Daré Bioscience, Inc.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
*Signature of Authorized Signatory of Investing Entity* : _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

**EXHIBIT B**

ASSIGNMENT FORM

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____

Phone Number: _____
(Please Print)

Email Address: _____

Dated: _____ ___, _____

Holder's Signature: _____

Holder's Address: _____

512267972v.2

**Exhibit 10.12**

# ROYALTY INTEREST FINANCING AGREEMENT

Dated as of December 21, 2023

between

UNITED IN ENDEAVOUR, LLC.

and

DARÉ BIOSCIENCE, INC.

This **ROYALTY INTEREST FINANCING AGREEMENT** (as amended, supplemented or otherwise modified from time to time, this "Agreement") is made and entered into as of December 21, 2023 by and between United in Endeavour, LLC, a limited liability company organized under the laws of the State of Georgia ("Investor"), and Daré Bioscience, Inc., a corporation organized under the laws of the State of Delaware ("Company").

**WHEREAS**, TriLogic Pharma, LLC, a limited liability company organized under the laws of the State of Delaware ("TriLogic") and MilanaPharm LLC, a limited liability company organized under the laws of the State of Delaware ("MilanaPharm") have entered into that certain License Agreement, dated April 5, 2013, pursuant to which TriLogic granted to MilanaPharm an exclusive royalty-free license, with the right to sublicense, certain intellectual property (the "TriLogic License"), and Company, TriLogic and MilanaPharm have entered into that certain Exclusive License Agreement, dated January 9, 2017, as amended December 5, 2018, December 3, 2019 and September 21, 2021, and as further amended and modified pursuant to that certain Consent, Waiver and Stand-By License Agreement, dated March 30, 2022, among the foregoing parties and Organon International GmBH, a limited liability company organized under the laws of Switzerland ("Organon" or "Sublicensee"), a copy of which existing as of the date hereof is attached hereto as Exhibit C (collectively, together with the TriLogic License, and as all of the foregoing may be hereafter amended, the "License Agreement"), pursuant to which, subject to the terms and conditions set forth therein, Company has been granted a license, with the right to grant sublicenses, to research, develop, make, have made, use, offer for sale, sell, import and commercialize XACIATO, an FDA-approved drug product for the treatment of bacterial vaginosis ("Xaciato" or "Xaciato Product");

**WHEREAS**, under the terms of that certain Exclusive License Agreement between Company and Organon, dated March 31, 2022, as amended July 4, 2023, a copy of which existing as of the date hereof is attached hereto as Exhibit A (as the same may be hereafter further amended, the "Sublicense Agreement"), subject to the terms and conditions set forth therein, Company has exclusively sublicensed to Organon certain of its rights under the License Agreement by granting Organon an exclusive license and sublicense, to among other things, commercialize the Xaciato Product in the Field in the Territory (each as defined below);

**WHEREAS**, Company wishes to sell, assign, convey and transfer to Investor, and Investor wishes to purchase and accept the assignment, conveyance, and transfer from Company, the Purchased Interest (as defined below) subject to the Hard Cap, upon and subject to the terms and conditions hereinafter set forth.

**NOW, THEREFORE,** in consideration of the mutual covenants, agreements representations and warranties set forth herein, the parties hereto agree as follows:

## Article I.
## DEFINITIONS

**Section 1.01 Definitions.**

The following terms, as used herein, shall have the following meanings:

"Affiliate" shall mean, with respect to a particular Party, any corporation or non-corporate business entity that, directly or indirectly, controls, is controlled by, or is under common control with such Party. For purposes of this definition, an entity will be regarded as in control of another entity (with correlative meanings for "controlled by" and "under common control with") if: (a) such entity owns, directly or indirectly, at least 50% of the securities or capital stock with the ability to vote to elect directors (or similar controlling management) of such entity, or has other comparable ownership and voting interest with respect to any entity

other than a corporation; or (b) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.

"Aggregate Investment Amount" shall mean the sum of the Initial Investment Amount and the Total Supplemental Discretionary Investment Amount.

"Agreement" shall have the meaning set forth in the Preamble.

"Anti-Corruption Laws" means all laws, rules, and regulations of any jurisdiction from time to time concerning or relating to bribery or corruption, including the United States Foreign Corrupt Practices Act of 1977 and the rules and regulations thereunder.

"Anti-Money Laundering Laws" means any and all applicable anti-money laundering or counter terrorist financing laws and regulations, including, without limitation, the Bank Secrecy Act of 1970, as amended, among others, by the Money Laundering Control Act of 1986, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (also known as the USA PATRIOT Act), and the Anti-Money Laundering Act of 2020; or any other United States law or regulation governing such activities; and the anti-money laundering and counter terrorist financing statutes of all applicable jurisdictions, the rules and regulations promulgated thereunder, and any related or similar applicable rules, regulations, or guidelines, issued, administered or enforced by any governmental entity (collectively, the "Anti-Money Laundering Laws").

"Applicable Law" means all applicable provisions of constitutions, laws, statutes, ordinances, rules, treaties, regulations, permits, licenses, approvals, interpretations and orders of any Governmental Authority with jurisdiction over the Licensed Products and all orders and decrees of all courts and arbitrators.

"Bankruptcy Event" shall mean the occurrence of any of the following in respect of Company:

(a) Company shall commence any case, proceeding or other action (i) under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization, relief of debtors or the like, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any portion of its assets, or Company shall make a general assignment for the benefit of its creditors;

(b) there shall be commenced against Company any case, proceeding or other action of a nature referred to in clause (i) above which remains undismissed, undischarged or unbonded for a period of sixty (90) calendar days;

(c) there shall be commenced against Company any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against (i) all or any substantial portion of its assets and/or (ii) the Xaciato Product or any substantial portion of the Intellectual Property related to the Xaciato Product, which results in the entry of an order for any such relief that shall not have been vacated, discharged, stayed, satisfied or bonded pending appeal within sixty (60) calendar days from the entry thereof; or

(d) Company shall take any corporate action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clause (a), (b) or (c) above.

"Business Day" shall mean any day other than a Saturday, Sunday, any day which is a legal holiday under the laws of the State of New York, or any day on which banking institutions located in the State of New York are required by law or other governmental action to close or are not otherwise open for banking business.

"Call Option" shall have the meaning set forth in Section 2.02(c).

"Call Closing Date" shall have the meaning set forth in Section 2.02(c).

"Call Payment" means the Hard Cap. For the avoidance of doubt, the Call Payment shall be calculated as of the date of the payment of the Call Payment.

"Change of Control" shall mean, with respect to Company (or any parent entity of Company), any (a) transaction of merger, consolidation or amalgamation with, or (b) sale of all or substantially all of the assets of Company (or such parent entity) to which this Agreement relates to, any other Person if (i) in the case of a transaction described in clause (a), Company (or such parent entity) is the continuing or surviving entity or (ii) in the case of a transaction described in clause (a) or clause (b), Company (or such parent entity) is not the continuing or surviving entity but the continuing or surviving entity (including the purchaser of all or substantially all of the assets of Company (or such parent entity) in the case of a transaction described in clause (b)) shall have assumed all of the obligations of Company under the Sublicense Agreement, the License Agreement, this Agreement and the other Transaction Documents to which Company is a party immediately prior to such transaction; providing that in each case (a) and (b), such transaction (and such assignments and assumptions) are completed in accordance with the applicable Sublicense Agreement and License Agreement (after obtaining any necessary consent of the Sublicensee and the Licensor and do not otherwise cause a breach or default under the Sublicense Agreement or the License Agreement.

"Claim" shall mean any claim, action or proceeding (including any investigation by any Governmental Authority).

"Company" shall have the meaning set forth in the Preamble.

"Company Common Stock" means shares of the common stock of the Company.

"Company Expenses" shall have the meaning set forth in Section 5.11.

"Company Indemnified Party" shall have the meaning set forth in Section 7.06(b).

"Confidentiality Agreement" shall mean, collectively, (a) that certain Confidentiality Agreement between Company and E. Adam Webb, dated August 4, 2023, and (b) that certain Confidentiality Agreement between Company and Mark S. Green, dated November 28, 2023.

"Confidentiality Breach" means, with respect to the disclosure of any notice, demand, certificate, correspondence, report, or other communication under the Sublicense Agreement or the License Agreement (or any information contained therein) to Investor, that such disclosure would be expected, in Company's reasonable judgment, to constitute a breach by Company of its confidentiality obligations under the Sublicense Agreement or License Agreement or owed to any Third Party.

"Confidential Information" shall mean, subject to the last sentence of Section 5.04(a), all information (whether written or oral, or in electronic or other form) of a confidential nature (i) furnished by Company to Investor on or after August 4, 2023 and on or prior to the Effective Date, or (ii) furnished by Company to Investor on or after the Effective Date and during the Term, in case of each of clause (i) and clause (ii) concerning, or relating in any way, directly or indirectly, to Company, the Purchased Interest, the Intellectual Property, the Licensed Product or the transactions contemplated by this Agreement or any of the Transaction Documents, including, without limitation:

(a) the License Agreement, the Sublicense Agreement, and any other agreements involving or relating in any way, directly or indirectly, to the Purchased Interest or the transactions contemplated by this Agreement or any of the Transaction Documents, including all terms and conditions thereof and the identities of the parties thereto;

(b) any reports (including, without limitation, royalty reports and Sales Reports received under the Sublicense Agreement), data, materials or other documents and any proprietary information of any kind relating in any way, directly or indirectly, to (I) Company, Licensee, Sublicensee, or any other counterparty to any of the agreements referenced in clause (a), (II) the Purchased Interest, (III) the transactions contemplated by this Agreement, (IV) the Intellectual Property (including the Intellectual Property of any Licensor or Sublicensee) (including, without limitation, any information relating to any proceeding, suit, claim, action, arbitration, litigation, challenge or similar matter that is threatened, pending or settled in any court, governmental agency or body, panel, tribunal or similar body with respect to any such Intellectual Property), (V) the Licensed Product or (VI) other products giving rise to the Purchased Interest, and including reports, notices, certificates, instruments, data, materials or other documents and proprietary information of any kind delivered pursuant to or under any of the agreements referred to in clause (a); and

(c) any technical and business information, including techniques, data, inventions, practices, methods, knowledge, know-how, test and trial data and results (including from pre-clinical and/or human clinical testing/trials), analytical and quality control data, costs, sales, manufacturing, patent data, any inventions, devices, improvements, formulations, discoveries, compositions, ingredients, patents, patent applications, processes, research, developments or any other Intellectual Property (including trade secrets) or information involving or relating in any way, directly or indirectly, to the Purchased Interests or the Licensed Product or other products giving rise to the Purchased Interest.

For the avoidance of doubt, this Agreement, the other Transaction Documents, the License Agreement, the Sublicense Agreement, and any notices or reports delivered by Company to Investor pursuant to this Agreement, including, but not limited to, Sales Reports and any other information or documents or materials provided by Company to Investor pursuant to this Agreement, shall be deemed to be Confidential Information, and Confidential Information shall also include all other proprietary information of Company. Confidential Information shall also include all analyses, compilations, forecasts, studies or other documents prepared by Investor, Investor's Affiliates or any of Investor's or Investor's Affiliates' representatives that contain, make use of or otherwise reflect any Confidential Information.

"Consent" shall mean any consent of Sublicensee, Licensor or any Third Party that is required for any Party hereto to execute, deliver, and/or perform this Agreement and the Transaction Documents.

"Dispute" shall have the meaning set forth in Section 3.12(j).

"Dollars" or "$" shall mean U.S. Dollars.

"Effective Date" means the date of this Agreement.

"Field" shall mean the "Field" as defined in the Sublicense Agreement.

"Financial Statements" shall have the meaning set forth in Section 3.05.

"Financing Statements" shall have the meaning set forth in Section 2.01(b).

"Fiscal Quarter" shall mean, for the first calendar quarter, the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

"Fiscal Year" shall mean (a) for the first such Fiscal Year, the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date occurs, (b) for each calendar year of the Payment Term thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the last year of the Payment Term, the period beginning on January 1 of the year in which this Agreement expires or terminates and ending on the effective date of expiration or termination of this Agreement.

"GAAP" shall mean United States generally accepted accounting principles as interpreted and accepted by the Financial Accounting Standards Board and the Securities and Exchange Commission, consistently applied through the applicable entity's organization.

"Governmental Authority" shall mean any government, court, regulatory or administrative agency or commission, or other governmental authority, agency, or instrumentality, whether foreign, federal, state, or local (domestic or foreign), including the Patent Office, the FDA, the United States National Institutes of Health, or any other government authority in any country.

"Hard Cap" shall mean, as of the applicable date of calculation, the amount that results in Investor receiving aggregate payments under this Agreement (including payments received by Investor in respect of the Purchased Interest and any prepayments made by Company to Investor pursuant to Section 2.02(a) of this Agreement) that achieves for Investor an internal rate of return of twelve percent (12%) (as calculated using the XIRR function in Microsoft Excel) on Investor's payment of the Initial Investment Amount and the Total Supplemental Discretionary Investment Amount, if any, paid by Investor to Company in respect of the Purchased Interest as of such date.

"Indemnified Party" shall mean any Investor Indemnified Party or Company Indemnified Party.

"Initial Investment Amount" shall have the meaning set forth in Section 2.03(a).

"Intellectual Property" shall have the meaning set forth in Section 3.12(a).

"Investor" shall have the meaning set forth in the Preamble.

"Investor Indemnified Party" shall have the meaning set forth in Section 7.06(a).

"Know-How" means all non-public information, results and data of any type whatsoever, in any tangible or intangible form (and whether or not patentable), including databases, practices,

methods, techniques, specifications, formulations, formulae, knowledge, skill, experience, data and results (including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical study data and results), analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

"Knowledge" shall mean (a) with respect to Company, the actual knowledge of Sabrina Johnson and Lisa Walters-Hoffert, and (b) with respect to Investor, the actual knowledge of E. Adam Webb and Mark S. Green.

"License Agreement" shall have the meaning set forth in the Recitals.

"Licensed Intellectual Property" shall have the meaning set forth inSection 3.12(a).

"Licensed Product" shall mean the "Licensed Product" identified in subsection (a) of the definition of "Licensed Product" in the Sublicense Agreement (i.e. "a thermosetting vaginal gel formulated with clindamycin phosphate two percent (2%) that is the subject of the first Daré Marketing Authorization, in any and all packaging alternatives (including as to quantity)").

"Licensor" shall mean MilanaPharm, and each of its successors and assigns.

"Liens" shall mean any lien, hypothecation, charge, instrument, preference, priority, security agreement, security interest, interest, mortgage, option, privilege, pledge, liability, covenant, order, tax, right of recovery, trust or deemed trust (whether contractual, statutory or otherwise arising) or any encumbrance, right or claim of any other person of any kind whatsoever whether choate or inchoate, filed or unfiled, noticed or unnoticed, recorded or unrecorded, contingent or non-contingent, material or non-material, known or unknown.

"Losses" shall mean collectively, any and all claims, damages, losses, judgments, liabilities, costs, and expenses (including reasonable attorneys' fees and expenses in connection with any action, suit or proceeding).

"Marketing Approval Application" shall mean an application for Regulatory Approval required before commercial sale or use of a Licensed Product as a medical product in a regulatory jurisdiction, including in the United States an NDA or PMA, or a prior approval supplement to an NDA or PMA or any amendments thereto submitted to the FDA with respect to a Licensed Product.

"Material Adverse Effect" shall mean (i) a Bankruptcy Event with respect to Company; (ii) a material adverse effect on the validity or enforceability of any of the Transaction Documents with respect to Company; (iii) a material adverse effect on the ability of Company to perform any of its material obligations under any of the Transaction Documents; (iv) a material adverse effect on the rights or remedies of Investor under any of the Transaction Documents with respect to Company; (v) a material adverse effect on the right of Investor to receive the Purchased Interest with respect to such Product; and (vi) a material adverse effect on the timing, amount or duration of the Royalties and Milestones with respect to such Product during the Payment Term.

"Material Contract" shall mean all material agreements, whether oral or written, express or implied, including, without limitation, assignments, licenses, options, franchise, distribution, marketing and manufacturing agreements, sponsorships, project agreements, collaboration agreements, joint development agreements, agreements not to enforce, consents, settlements, assignments, Liens or mortgages, and any amendments(s) renewal(s), novation(s) and termination(s) pertaining thereto, now, or hereafter entered into, including, without limitation,

the License Agreement and Sublicense Agreement, to which Company or any of Company's Affiliates is a party or any of Company's or its Affiliates' respective assets or properties are bound or committed (other than the Transaction Documents) relating to the Product, the termination of which would have a material adverse effect on the timing, amount, or duration of the Royalties and Milestones.

"Milestones" shall mean with respect to each Calendar Year beginning January 1, 2024 and during the Payment Term, the five "Sales Milestone Payments", if any, that become due and payable by Organon during the Payment Term pursuant to and in accordance with Section 6.2.2 of the Sublicense Agreement after giving effect to all adjustments, offsets, reductions, deductions, reimbursements, credits, and the like permitted to be taken pursuant to and in accordance with the Sublicense Agreement.

"NDA" shall mean a new drug application and all amendments and supplements thereto, submitted to the FDA with respect to the Product, including NDA 215650, approved by the FDA on December 7, 2021, and authorizing the U.S. marketing of XACIATO™ (clindamycin phosphate) vaginal gel for the treatment of Bacterial Vaginosis in female patients 12 years of age and older.

"Net Milestone Payments" shall mean with respect to each Calendar Quarter beginning January 1, 2024 and during the Payment Term, (i) all Milestones actually received by Company from Sublicensee under the Sublicense Agreement in the Calendar Quarter, *less* (ii) all amounts that are due and payable and actually paid by Company to the Sublicensee in accordance with the Sublicense Agreement in that Calendar Quarter, *less* (iii) all royalties, milestones, revenue shares and all other monetary amounts that are due and payable and actually paid by Company pursuant to and in accordance with the License Agreement in that Calendar Quarter; provided that the amounts set forth in (a)(ii)-(iii) above shall only be deducted from Milestones if and only to the extent such amounts have not already been deducted (and fully satisfied) from Royalties in calculating "Net Royalty Payments" (as defined below).

"Net Royalty Payments" shall mean with respect to each Calendar Quarter beginning January 1, 2024 and during the Payment Term, (i) all Royalties actually received by Company from Sublicensee under the Sublicense Agreement in the Calendar Quarter, *less* (ii) all amounts that are due and payable and actually paid by Company to the Sublicensee in accordance with the Sublicense Agreement in that Calendar Quarter, *less* (iii) all royalties, milestones, revenue shares and all other monetary amounts that are due and payable and actually paid by Company in accordance with the License Agreement and the Sublicense Agreement in that Calendar Quarter.

"Net Royalty/Milestone Payments" shall mean, collectively, the Net Royalty Payments and the Net Milestone Payments.

"Net Sales" shall mean the "Net Sales" in the "Territory" as each of those terms is defined in each of the Sublicense Agreement.

"OFAC" means the U.S. Department of the Treasury's Office of Foreign Assets Control.

"Organon" shall have the meaning set forth in the Recitals, and shall include its successors, and permitted assigns.

"Organon Consent" shall mean the consent of Organon substantially in the form of Exhibit B.

"Owned Intellectual Property" shall have the meaning set forth in Section 3.12(a).

"Party" shall mean, individually, Company and Investor, and unless otherwise indicated the "Parties" shall refer to Company and Investor collectively.

"Patent Office" shall mean the respective patent office, including the United States Patent and Trademark Office and any comparable foreign patent office, for any Patents for the Licensed Products in the Territory.

"Patents" shall mean the rights and interests in and to all issued patents and pending patent applications, including without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals, all letters patent granted thereon, and all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms (including regulatory extensions), and all supplementary protection certificates, together with any foreign counterparts thereof in the Territory in the Field relating to a Licensed Product, composition of matter, formulation, or methods of manufacture or use thereof that are issued or filed on or after the date hereof, including, without limitation, those identified in Schedule 3.12 in each case, which are owned or controlled by Company or any of its Affiliates.

"Payment Term" means the time period commencing on the Effective Date and expiring on the date upon which Investor has received in full cash payments in respect of the Purchased Interests totaling, in the aggregate, the Hard Cap.

"Person" shall mean an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, but not including a government or political subdivision or any agency or instrumentality of such government or political subdivision.

"Product" shall mean the Xaciato Product.

"Product Specific Patents" shall mean the Patents set forth onSchedule 3.12(a) and any other Patent in the Territory hereafter filed that are solely related to the Xaciato Product.

"Purchased Interest" shall mean Investor's right to receive from Company the percentage of the Net Royalty/Milestone Payments set forth in Exhibit D for each Fiscal Quarter during the Payment Term until Investor has received aggregate payments under this Agreement equal to the Hard Cap.

"Quarterly Report" shall mean, with respect to the relevant Fiscal Quarter, a report prepared by Company containing the amount payable to Investor with respect to the Purchased Interest for such Fiscal Quarter and for the 12 consecutive months ending with the last month of such quarter and showing in detail the basis for the calculation of such payments including, without limitation, (i) all Net Sales of the Licensed Products as reported in the applicable Sales Report, (ii) all payments of Milestones and Royalties paid by Sublicensee to Company in respect of such Net Sales of the Licensed Products as reported in the applicable Sales Report, and (iii) all payments payable with respect to such Fiscal Quarter to the Licensor and Sublicensee together with the calculation of such payments. Each Quarterly Report shall be accompanied by all Sales Reports provided by Sublicensee with respect to such Fiscal Quarter. Each Quarterly Report shall include reconciliation of such report to all information and data deliverable to Investor hereunder, together with relevant supporting documentation in Company's possession as Investor may reasonably request. Each Quarterly Report shall be delivered by Company to Investor within ninety (90) days of the end of each Fiscal Quarter.

"Rate of Interest" shall mean the interest rate equal to and for the 12 consecutive months ending with the last month of such quarter and showing in detail the basis for the calculation of

such payments the lesser of one and one-half percent (1.5%) per month or the maximum amount permitted by law.

"Receiving Party" shall have the meaning set forth in the definition of "Confidential Information".

"Regulatory Agency" shall mean a Governmental Authority with responsibility for the oversight and approval of the manufacture, use, storage, marketing, import, export, transport, offer for sale, or sale of medical products in a particular jurisdiction within the Territory.

"Regulatory Approval" shall mean all marketing approvals (including, without limitation, where applicable, pricing and reimbursement approval), establishment licenses, registrations, or other authorizations granted by any Governmental Authority, including and Marketing Approval Application necessary for the manufacture, use, storage, import, export, transport, offer for sale, or sale of any Licensed Product in a particular jurisdiction in the Field in the Territory in accordance with the Sublicense Agreement.

"Retained Interest" shall mean, individually and collectively: (a) all Royalties and Milestones paid, owed, accrued or otherwise payable by the Sublicensees under the Sublicense Agreements remaining after payment by Company to Investor of the Purchased Interest in accordance with this Agreement and the Transaction Documents; (b) all reimbursements, milestones, royalties, payments, fees, indemnification, damages, awards, settlement payments, or any other payments, compensation, or consideration of any kind pursuant to the Sublicense Agreement and the License Agreement other than the Purchased Interest, including but not limited to the First Commercial Sale Milestone set forth in Section 6.2.1 of the Sublicense Agreement.

"Royalties" shall mean with respect to each Calendar Year beginning January 1, 2023 (and payable for each Calendar Quarter beginning January 1, 2023) during the Payment Term, all royalties due and payable by Organon under Section 6.3 of the Sublicense Agreement on Net Sales of Xaciato in the Field in the Territory during such Calendar Quarter after giving effect to all adjustments, offsets, reductions, deductions, withholdings (including in respect of withholding Taxes required by Applicable Law), reimbursements, credits, and the like permitted to be taken pursuant to and in accordance with the Sublicense Agreement, including any interest payable by the Sublicensee under the Sublicense Agreement in connection with a late payment of such Royalties.

"Sales Report" shall mean, with respect to any Fiscal Quarter during the Payment Term, any report provided by or required to be provided by Sublicensee with respect to the Net Sales of the Product in the Field in the Territory in such Fiscal Quarter, including the notifications and reports required to be provided by Sublicensee to Company pursuant to Section 6.2.4(a) and Section 6.4 of the Sublicense Agreement in respect of the Milestones and Royalties.

"Sanctioned Country" means at any time, a country, region, or territory which is itself (or whose government is) the subject or target of any comprehensive Sanctions (including, as of the Effective Date, Cuba, Iran, North Korea, Syria, Crimea, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic).

"Sanctioned Person" means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by OFAC (including OFAC's Specially Designated Nationals and Blocked Persons List and OFAC's Consolidated Non-SDN List), the U.S. Department of State, the United Nations Security Council, the European Union, any European member state, or His Majesty's Treasury, (b) any Person operating, organized or resident in a Sanctioned Country, (c) any Person owned or controlled by, or acting or purporting to act for or

on behalf of, directly or indirectly, any such Person or Persons described in clauses (a) and (b), including a Person that is deemed by OFAC to be a Sanctions target based on the ownership of such legal entity by Sanctioned Person(s) or (d) any Person otherwise a target of Sanctions, including vessels and aircraft, that are designated under any Sanctions program.

"Sanctions" means any and all economic or financial sanctions, sectoral sanctions, secondary sanctions, trade embargoes and anti-terrorism laws, including but not limited to those imposed, administered or enforced from time to time by the U.S. government (including those administered by OFAC or the U.S. Department of State), the United Nations Security Council, the European Union, any European Union member state, or His Majesty's Treasury, or other relevant sanctions authority with jurisdiction over any Person or Persons.

"Sublicense Agreement" shall have the meaning set forth in the Preamble.

"Sublicensee" shall have the meaning set forth in the Preamble.

"Sublicensee/Licensor Confidential Information" shall mean the Confidential Information of the Sublicensee and/or the Licensor.

"Supplemental Discretionary Investment Amount 1" shall have the meaning set forth in Section 2.03(b)(i).

"Supplemental Discretionary Investment Amount 2" shall have the meaning set forth in Section 2.03(b)(ii).

"Supplemental Discretionary Investment Amount 3" shall have the meaning set forth in Section 2.03(b)(iii).

"Tax" or "Taxes" means any U.S. federal, state, local or non-U.S. tax, levy, impost, duty, assessment or withholding or other similar fee, deduction or charge, including all excise, sales, use, value added, transfer, stamp, documentary, filing, recordation and other fees imposed by any taxing authority (and interest, fines, penalties and additions related thereto).

"Territory" shall mean the "Territory" as defined in the Sublicense Agreement.

"Third Party" shall mean any Person other than Company or Investor or their respective Affiliates.

"Third Party Claim" shall have the meaning set forth in Section 7.06(c).

"Total Supplemental Discretionary Investment Amount" shall mean, at the time of calculation, (a) if Company has exercised its rights to receive payment of Supplementary Discretionary Investment Amount 1, Supplementary Discretionary Investment Amount 2, and/or Supplementary Discretionary Investment Amount 3 pursuant to Sections 2.03(b)(i) , Sections 2.03(b)(ii), and/or Sections 2.03(b)(iii), as applicable, and Investor has timely paid such amounts to Company pursuant to and in accordance with Section 2.03, then the amount equal to the total amount of such Supplemental Discretionary Investment Amounts that are timely paid to Company by Investor pursuant to and in accordance with Section 2.03, or (b) if Company has not exercised its right to receive payment of any Supplementary Discretionary Investment Amount pursuant to Sections 2.03(b)(i), Sections 2.03(b)(ii), and/or Sections 2.03(b)(iii), or Investor has failed to timely pay such amounts when due pursuant to and in accordance with Section 2.03, then the amount equal to $0.00. For the avoidance of doubt, the Total Supplementary Discretionary Investment Amount shall never be greater than $7,000,000.

"Transaction Documents" shall mean this Agreement.

"UCC" shall mean the Uniform Commercial Code (or any similar or equivalent legislation) as in effect in any applicable jurisdiction.

"Warrants" shall have the meaning set forth in Section 2.03(c).

"Xaciato" and "Xaciato Product" shall have the meaning set forth in the Recitals.

## Article II.
## PURCHASE AND SALE OF THE PURCHASED INTEREST

**Section 1.01 Purchase and Sale.**

Upon the terms and subject to the conditions set forth in this Agreement, on the Effective Date, Company shall sell, assign, transfer and convey to Investor, and Investor agrees to purchase and accept the assignment, transfer and conveyance from Company, and subject to the conditions set forth in Article VI, the Purchased Interest. Investor's interest in the Purchased Interest so assigned shall vest simultaneously with and only upon Company's receipt of the full, irrevocable, non-refundable, and non-deductible upfront payment pursuant to Section 2.03(a) for such Purchased Interest.

**Section 1.02 Payments to Investor.**

In consideration of the Investor paying the Investment Amount hereunder, the Company shall pay the Purchased Interests to the Investor as follows:

(a) Payments on Account of the Purchased Interest After cash in respect of Milestones and Royalties in respect of the Product is paid by the Sublicensee to Company and all payments required to be made by Company under the License Agreement and Sublicense Agreement have been made to the Licensor and Sublicensor in respect of the Product, Company shall determine the amount of Net Royalties and Net Milestone Payments and calculate the amount of the Purchased Interest due and owing to Investor and the amount of the Retained Interest due and owing to Company. During the Payment Term, Company shall make payments due and owing to Investor in respect of the Purchased Interest until the date on which the Investor has received payments in respect of the Purchased Interests equal to the Hard Cap. Company shall make such payments within fifteen (15) Business Days of Company's calculation of the amount of the Purchased Interest and shall provide Investor with a Quarterly Report setting forth such amount and the calculation thereof. To any extent funds paid by Sublicensee to Company are not actually deposited in an escrow account until such time as payments are made to Investor, such funds shall be treated as escrowed and off-limits for all other purposes until Investor has been paid all amounts owed therefrom. If any payment problems accrue due to such funds not being treated as escrowed funds, Investor shall promptly be made whole and the Parties agree to negotiate an appropriate escrow agreement to prevent any future such irregularities. Company shall have the right, at any time and from time to time, to make voluntary prepayments to Investor, and such payments shall be credited against the Hard Cap. This Agreement shall be in full force and effect for the duration of the Payment Term.

(b) Discrepancies. For avoidance of doubt, the Parties understand and agree that if a Sublicensee fails to pay any Milestones or Royalties (or portion thereof) during the Payment Term when due under the Sublicense Agreement (each such unpaid amount, a "Discrepancy"), then Company shall not be obligated to pay to Investor or otherwise compensate or make Investor whole with respect to any portion of such Discrepancy; provided, however, that Company shall, at Investor's reasonable request and upon reasonable consultation with Investor,

enforce the terms of the Sublicense Agreement in accordance with Company's exercise of its reasonable business judgment, and upon any recovery of a Discrepancy, and the determination of the amount of such Discrepancy due and owing to Investor in respect of any unpaid portion of the Purchased Interest, Company shall transfer such portion of such Discrepancy in respect of the Purchased Interest to Investor as set out in Section 2.02(a).

(c) Call Option. The Company shall have the right, but not the obligation, at any time (the "Call Option"), exercisable upon ten (10) days' prior written notice to Investor, to repurchase all, but not less than all, of the Purchased Interest from the Investor at a repurchase price equal to the Call Payment. In order to exercise the Call Option, the Company shall deliver written notice to Investor of its election to so repurchase the Purchased Interest not less than ten (10) days prior to the proposed closing date (the "Call Closing Date"); provided, however, that such notice may state that it is conditioned upon the effectiveness of any financing transaction or one or more other events specified therein (including the occurrence of a Change of Control), in which case such notice may be revoked by the Company (by notice to the Investor no later than five (5) days prior to the specified effective date) if such condition is not satisfied. On the Call Closing Date, the Company shall repurchase from the Investor the Purchased Interest at a price equal to the Call Payment, the payment of which shall be made by wire transfer of immediately available funds to the account designated by Investor.

(d) Payment Terms. The payments to be made by Company to Investor pursuant to this Section 2.02 shall be paid by wire transfer of immediately available funds to the account designated by Investor. In the event any amount due to Investor hereunder in respect of the Purchased Interest (other than any Discrepancy) is not made when due, each such amount shall accrue interest from the date due at the Rate of Interest, calculated on the basis of a 360-day, 12-month year, until payment is actually made to Investor.

(e) Termination of Purchased Interest. Once the Investor has received (i) aggregate payments under Section 2.02(a) equal to the Hard Cap or (ii) all of the amounts due pursuant to and in accordance with Section 2.02(c), (x) Company shall have no further obligations to the Investor with respect to the Purchased Interests, and Investor will not be entitled to any additional payments in respect of the Purchased Interests and (y) each of the Transaction Documents shall terminate. Immediately upon termination of this Agreement pursuant to this Section 2.02(e), Investor shall execute and deliver to, or at the direction of, the Company, at the Company's sole cost and expense, all other releases and other documents as the Company shall reasonably request to evidence any such release.

**Section 1.03 Payments to Company.**

(a) Initial Payment for Purchased Interest. In consideration for the sale and assignment by Company to Investor of the Purchased Interest, and subject to the terms and conditions set forth herein, including, without limitation, Section 6.01, on the Effective Date, Investor shall make an irrevocable, non-refundable, and non-deductible payment to Company of Five Million Dollars ($5,000,000.00), without any deduction for any withholding or other Taxes (the "Initial Investment Amount").

(b) Supplemental Investment Amount (Company's Option). In consideration for the sale and assignment by Company to Investor of the Purchased Interest, and subject to (x) the terms and conditions set forth herein, including, without limitation, Section 6.01, and (y) the Company having obtained the Organon Consent (including, for the avoidance of doubt, the Investor as a "Purchaser" thereunder):

i) at any time between January 1, 2024 through December 31, 2026, Company may in its sole discretion elect to exercise its right to receive, and upon such election in

writing by Company, Investor shall make to Company, an irrevocable, non-refundable, and non-deductible payment of up to Three Million Dollars ($3,000,000.00) (such amount so elected by Company and paid by Investor to Company, the "Supplemental Discretionary Investment Amount 1") within twenty (20) Business Days of the date of such notice;

ii) at any time between January 1, 2024 through December 31, 2026, Company may in its sole discretion elect to exercise its right to receive, and upon such election in writing by Company, Investor shall make to Company, a second irrevocable, non-refundable, and non-deductible payment of up to Three Million Dollars ($3,000,000.00) (such amount so elected by Company and paid by Investor to Company, the "Supplemental Discretionary Investment Amount 2") within twenty (20) Business Days of the date of such notice;

iii) at any time between January 1, 2024 through December 31, 2026, Company may in its sole discretion elect to exercise its right to receive, and upon such election in writing by Company, Investor shall make to Company, a third irrevocable, non-refundable, and non-deductible payment of up to Three Million Dollars ($3,000,000.00) (such amount so elected by Company and paid by Investor to Company, the "Supplemental Discretionary Investment Amount 3") within twenty (20) Business Days of the date of such notice; provided that the amount of the Supplemental Discretionary Investment Amount 3 shall not exceed an amount that would cause the Total Investment Amount to exceed Twelve Million Dollars ($12,000,000.00).

(c) Warrants. Upon funding the Initial Investment Amount, Company shall issue to Investor a warrant to purchase 5,000,000 shares of Company Common Stock in substantially the form attached hereto as Exhibit F (the "Closing Warrant"). If Company exercises its right receive any Supplemental Discretionary Investment Amount in accordance with Section 2.03(b), then, upon receipt of such payment, Company shall issue to Investor a warrant to purchase Company Common Stock in substantially the form attached hereto as Exhibit F (each, a "Supplemental Investment Warrant" and, together with the Closing Warrant, the "Warrants") for a number of shares equal to 1,000,000 (as adjusted in accordance with Section 3(a) of the Warrant) for each $1,000,000 received. Any fundings which are not in even million-dollar increments shall accrue warrants pro-rata (e.g., $2,400,000/2,400,000 shares). For avoidance of doubt, the total number of shares that may become issuable under this Section 2.03(c) shall not exceed 12,000,000 (as adjusted in accordance with Section 3(a) of the Warrant).

(d) Payment Procedure. The payments to be made by Investor to Company pursuant to this Section 2.03 shall be paid by wire transfer of immediately available funds to the account(s) designated by Company. The Initial Investment Amount, the Supplemental Discretionary Investment Amount 1, as applicable, the Supplemental Discretionary Investment Amount 2, as applicable, and the Supplemental Discretionary Investment Amount 3, as applicable, will be non-creditable and non-refundable, and notwithstanding any provision to the contrary set forth in this Agreement, will not be subject to any withholding or offset or reduction for any Tax.

**Section 1.04 No Assumed Obligations.**

Notwithstanding any provision in this Agreement or any other Transaction Document or writing to the contrary, Investor is accepting the purchase and assignment of only the Purchased Interest and is not assuming any liability or obligation of Company or any of its Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, whether known or unknown, and whether under the Sublicense Agreements or otherwise (the "Excluded

Liabilities and Obligations"). All such Excluded Liabilities and Obligations shall be retained by and remain obligations and liabilities solely of Company or its Affiliates.

## Article III.
## REPRESENTATIONS AND WARRANTIES OF COMPANY

Company, hereby represents and warrants to Investor the following:

**Section 1.01 Organization.**

Company is a corporation duly incorporated, validly existing, and in good standing under the laws of the state of Delaware, and has all corporate powers and all licenses, authorizations, consents and approvals required in connection with the transactions contemplated by the Transaction Documents.

**Section 1.02 Entity Authorization.**

Company has all necessary power and authority to enter into, execute and deliver the Transaction Documents to which it is a party and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. The Transaction Documents have been duly authorized, executed and delivered by Company and each Transaction Document constitutes the valid and binding obligation of Company, enforceable against Company in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting creditors' rights generally or general equitable principles.

**Section 1.03 Governmental Authorization.**

The execution and delivery by Company of the Transaction Documents, and the performance by Company of its obligations hereunder and thereunder, does not require any notice to, action or consent by, or in respect of, or filing with, any Governmental Authority.

**Section 1.04 Ownership Intellectual Property Related to the Purchased Interest.**

(a) To the Knowledge of Company, Company owns, or holds a valid license under, all of the Intellectual Property, subject to the rights of the Licensor under the License Agreement and the rights of the Sublicensee under the Sublicense Agreement, and no license or covenant not to sue under any Intellectual Property or Regulatory Approvals with respect to any Licensed Product has been granted by Company to any Third Party in the Territory, with the exception of the rights granted to the Sublicensee under the Sublicense Agreement and the rights granted to the Licensor under the License Agreement.

(b) (i) Company, as of immediately prior to the sale and assignment of the Purchased Interest as provided herein, was and through the terms of the Sublicense Agreement continued to be, the sole holder of, the Purchased Interest; (ii) Company has not transferred, sold, conveyed, assigned, or otherwise disposed of, or agreed to transfer, sell, convey, assign, or otherwise dispose of any portion of the Milestones or Royalties other than as contemplated by this Agreement; (iii) no Person other than Company has any right to receive the payments payable under the Sublicense Agreement, other than Investor's rights with respect to the Purchased Interest, from and after the Effective Date; (iv) Company has the full right to sell, transfer, convey and assign to Investor all of its rights and interests in and to the Purchased Interest without any requirement to obtain the consent of any Person which has not been obtained; and (vi) subject to the payment by Investor to Company pursuant to Section 2.03(a).

**Section 1.05 Financial Statements.**

Company has provided to Investor its audited balance sheets as of December 31, 2021 and December 31, 2022, and the related audited statements of operations, stockholders' equity, and cash flows of Company for the year ended December 31, 2021 and 2022, and the unaudited consolidated balance sheet of Company and its Subsidiaries at September 30, 2023 and the related unaudited consolidated statements of operations and cash flows of Company and its Subsidiaries for the fiscal quarter ended September 30, 2023 and the accompanying footnotes thereto (such sheets and statements and footnotes, the "Financial Statements"). The Financial Statements are complete and accurate in all material respects, were prepared in accordance with GAAP and present fairly in all material respects the financial position and the financial results of Company as of the dates and for the periods covered thereby.

**Section 1.06 No Undisclosed Liabilities.**

Except for those liabilities (i) specifically identified in the Financial Statements, (ii) incurred by Company in the ordinary course of business since September 30, 2023, or (iii) in connection with Company's obligations under the Transaction Documents, there are no material liabilities of Company of any kind whatsoever, whether accrued, contingent, absolute, determined, or determinable, except as would not reasonably be expected to result in a Material Adverse Effect. The Company agrees that it has not previously and shall never in the future borrow against or assign any portion of its interest in the funds to be paid by Sublicensee to Company for the Xaciato Product to any third party without advance disclosure and written approval of Investor.

**Section 1.07 Solvency.**

Assuming consummation of the transactions contemplated by the Transaction Documents, (i) the present fair saleable value of assets of Company is greater than the amount required to pay its debts as they become due, (ii) Company does not have unreasonably small capital with which to engage in its business, and (iii) Company has not incurred, nor does Company have present plans to or intend to incur, debts or liabilities beyond its ability to pay such debts or liabilities as they become absolute and matured.

**Section 1.08 Litigation.**

There is no (i) action, suit, arbitration proceeding, claim, investigation or other proceeding pending against Company or, to the Knowledge of Company, threatened against Company, or, to the Knowledge of Company, pending or threatened against the Licensor or Sublicensee or (ii) governmental inquiry pending or, to the Knowledge of Company, threatened against Company, or, to the Knowledge of Company, the Licensor or the Sublicensee, in each case with respect to clauses (i) and (ii) above, which, if adversely determined, would reasonably be expected to result in a Material Adverse Effect. There is no action, suit, claim, proceeding or investigation pending or, to the Knowledge of Company, threatened against Company, or to the Knowledge of Company, pending or threatened against the Licensor or the Sublicensee or any other Person, relating to the Royalties and Milestones, which, if adversely determined, in each case that would reasonably be expected to result in a Material Adverse Effect.

**Section 1.09 Compliance with Laws.**

(a) Company (i) is not in violation of, has not violated, or to the Knowledge of Company, is not under investigation with respect to, and (ii) has not been, or to the Knowledge of Company, threatened to be, charged with or been given notice of any violation of any law, rule, ordinance or regulation of, or any judgment, order, writ, decree, permit or license entered by

any Governmental Authority applicable to Company, the Royalties or the Milestones that would reasonably be expected to result in a Material Adverse Effect.

(b) As of the Effective Date, Company, or to the knowledge of Company, any of its directors, officers, employees, agents, representatives or Affiliates (i) is a Sanctioned Person or currently the subject or target of any Sanctions, (ii) has its assets located in a Sanctioned Country, (iii) is under administrative, civil or criminal investigation for an alleged violation of, or received notice from or made a voluntary disclosure to any governmental entity regarding a possible violation of, Anti-Corruption Laws, Anti-Money Laundering Laws or Sanctions by a governmental authority that enforces Sanctions or any Anti-Corruption Laws or Anti-Money Laundering Laws, or (iv) directly or indirectly derives revenues from investments in, or transactions with, Sanctioned Persons in violation of any Sanctions.

**Section 1.10 Conflicts.**

Neither the execution and delivery of any of the Transaction Documents nor the performance or consummation of the transactions contemplated hereby and thereby will: (i) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (A) any law, rule, ordinance or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which Company or any of its assets or properties may be subject or bound; or (B) any contract, agreement, commitment or instrument to which Company is a party or by which Company or any of its assets or properties is bound or committed; (ii) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the certificate of incorporation or by-laws of Company; (iii) require any notification to, filing with, or consent of, any Person or Governmental Authority other than the consents obtained by Company prior to the Closing; or (iv) give rise to any right of termination, cancellation or acceleration of any right or obligation of Company or any other Person or to a loss of any benefit relating to the Purchased Interest; in each case (i)-(iv) above, which would reasonably be expected to result in a Material Adverse Effect.

**Section 1.11 [Reserved].**

**Section 1.12 Intellectual Property.**

(a) Schedule 3.12(a) sets forth an accurate, true and complete list (by category and family) of all (i) Patents (including pending Patent applications) and utility models, (ii) trade names, common law trademarks, common law service marks, registered trademarks, registered service marks, and applications for trademark registration or service mark registration, (iii) registered and unregistered copyrights and (iv) domain name registrations and websites, in each case with respect to clauses (i), (ii), (iii) and (iv) above in this subsection (a) that are owned, controlled by, issued to, licensed to, licensed by or hereafter acquired by or licensed by Company that are necessary or used to make, have made, use, sell, have sold, offer for sale, import, develop, promote, market, distribute, manufacture, commercialize or otherwise exploit the Xaciato Product in the Field in the Territory (collectively, the "Intellectual Property"). Schedule 3.12(a) identifies the Intellectual Property that is owned exclusively by Company (the "Owned Intellectual Property") and the Intellectual Property that is in-licensed to Company pursuant to the License Agreement (the "Licensed Intellectual Property"). For each item of Intellectual Property listed on Schedule 3.12(a), Schedule 3.12(a) accurately identifies, as applicable, (i) the owner, (ii) the countries in which such listed item is patented or registered or in which an application for Patent or registration is pending, (iii) the application number, (iv) the Patent or registration number, (v) the expected expiration date, as applicable, including any applicable term extensions or supplemental protection certificates, if applicable, and (vi) the earliest relied

upon priority filing date used to calculate the expiration date. To the Knowledge of Company, except as disclosed therein, each item of Intellectual Property listed on Schedule 3.12(a) is valid, enforceable, and subsisting and no Intellectual Property listed on Schedule 3.12(a) has lapsed, expired, been cancelled, or become abandoned, except in the ordinary course of prosecution. To the Knowledge of Company, each of the issued U.S. Patents listed in Schedule 3.12(a) correctly identifies each and every inventor thereof as determined in accordance with the laws of the United States.

(b) Schedule 3.12(b) sets forth an accurate, true and complete list of all Material Contracts pursuant to which Company has the legal right to exploit intellectual property that is owned by another Person or a Third Party with respect to the Licensed Product in the Territory. There are no unpaid fees or royalties under any agreement listed on Schedule 3.12(b) that have become due, or are expected to become overdue, as of the Effective Date, other than amounts required to be paid to Licensor under the License Agreement and to the Sublicensee under the Sublicense Agreement.

(c) Each agreement listed in Schedule 3.12(b) is legal, valid, binding, enforceable, and in full force and effect. Company is not in material breach of such listed agreements, and, to the Knowledge of Company, no circumstances or grounds exist that would give rise to a claim of breach or right of rescission, termination, revision, or amendment of any of the agreements specified in Schedule 3.12(b), including, without limitation, the execution, delivery and performance of this Agreement and the other Transaction Documents.

(d) Except for Intellectual Property licensed to Company pursuant to any agreement listed on Schedule 3.12(b) and the Owned Intellectual Property, to the Knowledge of Company, no other Intellectual Property is necessary for the Sublicensee to make or have made the Xaciato Product in the Field in the Territory and to offer to sell, have sold, use, import, distribute, commercialize, or market Xaciato in the Field in the Territory. To the Knowledge of Company, the manufacture, use or sale of the Xaciato Product in the Field in the Territory by the Sublicensee as contemplated in the Sublicense Agreement does not infringe upon any valid and enforceable Third Party's patents. Company has not received any written notice from a Third Party alleging, and to the Knowledge of Company, no Third Party has alleged, that the manufacture, use or sale of the Xaciato Product the by the Sublicensee in the Field in the Territory infringes on any patent rights of a Third Party.

(e) Company possesses the sole, exclusive, valid, marketable and unencumbered title to the Owned Intellectual Property listed on Schedule 3.12(a); all assignments from each inventor of the Owned Intellectual Property to Company, have been executed and recorded in the United States Patent and Trademark Office for each of the Patents comprising Owned Intellectual Property; there are no recorded Liens on or to any Owned Intellectual Property listed on Schedule 3.12(a) other than the agreements listed on Schedule 3.12(b).

(f) Company has the full right, power, and authority to grant all of the rights and interests granted to Investor in this Agreement and to the Sublicensee under the Sublicense Agreement.

(g) There are no unpaid maintenance, annuity, or renewal fees currently overdue for any of the Owned Intellectual Property listed on Schedule 3.12(a), nor have any applications or registrations therefor lapsed or become abandoned, been cancelled, or expired except in the ordinary course of prosecution.

(h) There is no pending, decided or settled opposition, interference proceeding, reexamination proceeding, cancellation proceeding, injunction, claim, lawsuit, proceeding, hearing, investigation, complaint, arbitration, mediation, demand, International Trade

Commission investigation, decree, or any other dispute, disagreement, or claim to which Company is or was a party (collectively referred to hereinafter as "Disputes"), nor has any such Dispute to the knowledge of Company been threatened in writing, challenging the legality, validity, enforceability or ownership of any Intellectual Property or which would give rise to a credit against the Royalties or Milestones under the Sublicense Agreement.

(i) There is no pending or, to Company's Knowledge, threatened action, suit, or proceeding, or any investigation or claim by any Governmental Authority to which Company is a party (1) that is the subject of a claim for indemnification by any Person or Third Party under any Material Contract, or (2) that the marketing, sale or distribution of the Licensed Product in the Field in the Territory by Company or the Sublicensee infringes on any patent or other intellectual property rights of any other Person.

**Section 1.13 Regulatory Approval.**

(a) Company is in material compliance with, and has materially complied with, all applicable federal, state, local and foreign laws, rules, regulations, standards, orders and decrees governing its business, including all regulations promulgated by each Regulatory Agency in the territory in which Company operates or engages in activities in connection with the Licensed Products the failure of compliance with which could reasonably be expected to result in a Material Adverse Effect; Company has not, and to the Knowledge of Company, the Sublicensee has not, received any notice citing action or inaction by any of them that would constitute any material non-compliance with any applicable federal, state, local and foreign laws, rules, regulations that would reasonably be expected to result in a Material Adverse Effect.

(b) The studies, tests and preclinical and clinical trials conducted relating to the Licensed Product have been conducted in all material respects in accordance with experimental protocols and Applicable Laws; the descriptions of the results of such studies, tests and trials are accurate in all material respects; and Company has not received any notices or correspondence from any Regulatory Agency requiring the termination, suspension, or material modification or clinical hold of any such studies, tests or preclinical or clinical trials conducted by or on behalf of Company or the Sublicensee, which termination, suspension, material modification or clinical hold could reasonably be expected to result in a Material Adverse Effect.

**Section 1.14 Material Contracts.**

(a) Except as set forth on Schedule 3.14, there are no Material Contracts other than the License Agreements and the Sublicense Agreements. Company is not in breach of or in default under any Material Contract, which default, individually or in the aggregate, would result in a Material Adverse Effect. Company has not received any notice of any threat of termination of any such Material Contract. To the Knowledge of Company, no other party to a Material Contract is in breach of or in default under such Material Contract. All Material Contracts are valid and binding on Company and, to the Knowledge of Company on each other party thereto, and are in full force and effect. The Company agrees that it has not previously and shall never in the future borrow against or assign any portion of its interest in the funds to be paid by Sublicensee to Company for the Xaciato Product to any third party without advance disclosure and written approval of Investor.

(b) Without limiting the generality of the foregoing, with respect to the License Agreement and Sublicenses Agreement:

(i) Attached hereto:

(1) As Exhibit A is a true and complete copy of the Sublicense Agreement, as amended through the Effective Date;

(2) As Exhibit C is a true and complete copy of the License Agreement, as amended through the Effective Date;

(ii) Company nor, to the Knowledge of Company, the Licensor or the Sublicensee, has impaired, waived, altered, or modified in any material respect, whether by way of any sublicense or consent or otherwise, the License Agreement or Sublicense Agreement, respectively. To the Knowledge of Company, Sublicensee has not granted any sublicense under or with respect to the Sublicense Agreement.

(iii) Company has not released in any material respect (a) the Licensor, in whole or in part, from any of its obligations under the License Agreement, or (b) the Sublicensee, in whole or in part, from any of its obligations under the Sublicense Agreement.

(iv) Company has not received any written notice from (a) the Licensor terminating, or requesting any amendment, alteration, modification, or termination of the License Agreement, nor has the Licensor indicated or communicated to Company any desire or intent to do so, or (b) the Sublicensee terminating, or requesting any amendment, alteration, modification, or termination of the Sublicense Agreement, nor has the Sublicensee indicated or communicated to Company any desire or intent to do so.

(v) [Reserved].

(vi) To the Knowledge of Company, no event has occurred, and no condition exists that would materially adversely affect the right of Company to receive Royalties and Milestones payable under the Sublicense Agreement. Company has not taken any action or omitted to take any action, that would adversely affect the right of Company to receive Royalties and Milestones payable under the Sublicense Agreement.

(vii) The License Agreement is enforceable against Company and, to the Knowledge of Company, the Licensor thereunder, in accordance with its terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally. The execution, delivery and performance of the License Agreement was and is within the corporate powers of Company and, to the Knowledge of Company, the Licensor. The License Agreement was duly authorized by all necessary action on the part of, and validly executed and delivered by, Company and, to the Knowledge of Company, the Licensor. There is no material breach or default, or event which, upon notice or the passage of time, or both, would give rise to any material breach or default, in the performance of the License Agreement by Company or, to the Knowledge of Company, the Licensor.

(viii) The Sublicense Agreement is enforceable against Company and, to the Knowledge of Company, the Sublicensee thereunder, in accordance with its terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally. The execution, delivery and performance of the Sublicense Agreement was and is within the corporate powers of Company and, to the Knowledge of Company, the Sublicensee. The Sublicense Agreement was duly authorized by all necessary action on the part of, and validly executed and delivered by, Company and, to the Knowledge of Company, the Sublicensee. There is no breach or default, or event which, upon notice or the passage of

time, or both, could give rise to any breach or default, in the performance of the Sublicense Agreement by Company or, to the Knowledge of Company, the Sublicensee.

(ix) To the Knowledge of Company, except as set forth in the Sublicense Agreement, the Sublicensee has no right of set-off against any Royalties or Milestones or any other amount payable to Company under the Sublicense Agreement other than as expressly set forth in the Sublicense Agreement.

(x) Sublicensee has not provided written notice to Company of any intention to replace a Licensed Product with an alternative product or reduce materially its efforts to develop and commercialize the Licensed Products.

(xi) Schedule 3.14 annexed hereto sets forth to Company's Knowledge a true and complete copy of all Sales Reports provided by Sublicensee to Company through September 30, 2023.

**Section 1.15 Name, State of Formation or Organization, and Principal Place of Business**

The full legal name, state of incorporation and principal place of business of Company is set forth on Schedule 3.15.

**Section 1.16 Broker's Fees.**

Other than fees payable to Cowen and Company, LLC, financial advisor to Company, neither Company nor any Affiliate of Company has taken any action that would entitle any Person to any commission or broker's fee in connection with the transactions contemplated by the Transaction Documents.

**Section 1.17 Taxes.**

No deduction or withholding for or on account of any Tax has been made from any payment by Sublicensee to Company under the Sublicense Agreement.

**Section 1.18 Bankruptcy Event.**

No Bankruptcy Event has occurred with respect to Company or, to the Knowledge of Company, with respect to the Licensor or the Sublicensee.

**Section 1.19 Material Adverse Effect.**

Since September 30, 2023, to the Knowledge of Company, no event has occurred which with the passage of time and/or the giving of notice would constitute a Material Adverse Effect.

## Article IV.
## REPRESENTATIONS AND WARRANTIES OF INVESTOR

Investor represents and warrants to Company the following:

**Section 1.01 Organization.**

Investor is a limited liability company duly organized and validly existing under the laws of the State of Georgia.

**Section 1.02 Authorization.**

Investor has all necessary power and authority to enter into, execute and deliver the Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. The Transaction Documents have been duly authorized, executed and delivered by Investor and each Transaction Document constitutes the valid and binding obligation of Investor, enforceable against Investor in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting creditors' rights generally or general equitable principles.

**Section 1.03 Broker's Fees.**

Investor has not taken any action that would entitle any Person to any commission or broker's fee in connection with the transactions contemplated by the Transaction Documents.

**Section 1.04 Conflicts.**

Neither the execution and delivery of this Agreement or any other Transaction Document nor the performance or consummation of the transactions contemplated hereby or thereby will: (i) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (A) any law, rule or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which Investor or any of its assets or properties may be subject or bound; or (B) any contract, agreement, commitment or instrument to which Investor is a party or by which Investor or any of its assets or properties is bound or committed; (ii) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the organizational or constitutional documents of Investor; or (iii) require any notification to, filing with, or consent of, any Person or Governmental Authority.

**Section 1.05 Tax Status.**

Investor is exempt from United States federal withholding Tax on all payments with respect to the Purchased Interest by reason of being a "United States person", as such term is defined in Section 7701(a)(30) of the Code (a "U.S. Person"). Investor is acting as a principal, and not as an agent for any other Person, in connection with the execution, delivery, and performance by Investor of the Transaction Documents and the consummation of the transactions contemplated thereby.

**Section 1.06 Access to Information.**

Investor acknowledges that it has (a) reviewed the License Agreement and the Sublicense Agreement, the Warrant and such other documents and information that were requested by Investor and provided to Investor by Company and (b) had the opportunity to ask such questions of, and to receive answers from, representatives of Company concerning the License Agreement and the Sublicense Agreement, Company's business and financial condition and such other documents and information, in each case, as it deemed necessary to make an informed decision to purchase, acquire, and accept the Purchased Interest and the Warrant in accordance with the

terms of this Agreement. Investor has such knowledge, sophistication, and experience in financial and business matters that it is capable of evaluating the risks and merits of purchasing, acquiring, and accepting the Purchased Interest and the Warrant in accordance with the terms of this Agreement. Company has not made any representation or warranty, express or implied, as to the accuracy or completeness of any information concerning the Milestones, Royalties, Purchased Interest, the License Agreement, the Sublicense Agreement, the Intellectual Property, the Products, the Licensor, the Sublicensee, or any other matter, except as expressly set forth in this Agreement, and Company expressly disclaims any and all liability that may be based on such information or errors therein or omissions therefrom. Investor has not relied and is not relying on any statement, representation, or warranty, oral or written, express or implied (including any representation or warranty as to merchantability or fitness for a particular purpose), made by Company, except as expressly set forth in Article III. Neither Company nor any of its Affiliates or representatives will have any liability to Investor or any of its Affiliates or representatives resulting from the use of any information, documents, or materials made available to Investor, whether orally or in writing, in any confidential information memoranda, market surveys, financial projections, "data rooms", due diligence discussions, or in any other form in expectation of the transactions contemplated by this Agreement, and Investor acknowledges and agrees that all information provided by or on behalf of Company to Investor prior to the Effective Date has been provided "AS IS". Company is not making, directly or indirectly, any representation or warranty with respect to any estimates, projections, or forecasts involving the Milestones, Royalties, Purchased Interest, or Purchased Interest, the License Agreements, the Sublicense Agreements, the Intellectual Property, the Products, the Licensors, the Sublicensees, or any other matter. Investor acknowledges that there are inherent uncertainties in attempting to make such estimates, projections, and forecasts and that it takes full responsibility for making its own evaluation of the adequacy and accuracy of any such estimates, projections, or forecasts (including the reasonableness of the assumptions underlying any such estimates, projections, and forecasts). Investor acknowledges that Investor will acquire the Purchased Interest on an "as-is" and "where-is" basis, except as expressly set forth in Article III. Investor acknowledges and agrees that the representations and warranties in Article III are the result of arms'-length negotiations between sophisticated parties. Investor has no Knowledge or reason to believe that any of the representations or warranties made by Company as of the Effective Date are untrue, incomplete, or inaccurate.

## Article V.
## COVENANTS

During the Payment Term, the following covenants shall apply:

**Section 1.01 Consents and Waivers.**

The Parties shall work together to use commercially reasonable efforts to obtain and maintain any required Consents, acknowledgements, certificates, or waivers, at Investor's cost and expense, to the extent necessary so that the transactions contemplated by this Agreement, or any other Transaction Document may be consummated and performed and shall not result in any material default, material breach or termination of any of the Material Contracts.

**Section 1.02 Access; Information.**

(a) Promptly after receipt by Company or any Affiliate of Company of notice of any action, claim, investigation, proceeding (commenced or threatened), certificate, offer, proposal, material correspondence or other material written communication relating to the transactions contemplated by this Agreement, any other Transaction Document, the Purchased Interest, or any License Agreement or Sublicense Agreement, then, Company shall inform Investor of the receipt of such notice and the substance of such action, claim, investigation, proceeding, certificate,

offer, proposal, correspondence or other written communication and, if in writing shall, furnish Investor with a copy of such notice and any related materials with respect to such action, claim, investigation, proceeding, certificate, offer, proposal, correspondence or other written communication, in each case, to the extent such action would not constitute a Confidentiality Breach.

(b) Company shall keep, maintain, and exercise any rights it has under the Sublicense Agreement to cause the Sublicensee to keep and maintain, at all times full and accurate books of account and records adequate to reflect correctly all payments paid and/or payable with respect to the Royalties and the Milestones. In the event that the Sublicensee does not provide copies of any Sales Report to Investor, upon Investor's reasonable request and at Investor's expense, Company shall provide Investor with copies of all Sales Reports received by Company pursuant to the Sublicense Agreement, to the extent such action would not constitute a Confidentiality Breach. Company shall, upon Investor's reasonable request and at Investor's expense, exercise any rights they have under the Sublicense Agreement to audit the books and records of each Sublicensee subject to the terms and conditions of the Sublicense Agreement. Within a reasonable time after completion of any audit of any Sublicensee, Company shall deliver to Investor a copy of any audit report received by Company pursuant to the Sublicense Agreement summarizing the results of such audit, to the extent such action would not constitute a Confidentiality Breach.

(c) Investor and any of its representatives shall have the right, from time to time, to visit Company or Company's Affiliate's offices and properties where books and records relating or pertaining to the Royalties, Milestones, and Purchased Interest are kept and maintained for purposes of conducting an audit of such books and records with respect thereto, and to inspect, copy and audit such books and records, during normal business hours; provided that no more than one such audit with respect to the Products collectively shall be conducted in any Calendar Year. Upon ten (10) Business Days' written notice by Investor, Company shall provide or shall cause its Affiliates to provide to Investor or any of its representatives reasonable access to such books and records, and shall permit Investor and its representatives to discuss the business, operations, properties and financial and other condition of Company, with respect to matters relating to the Royalties, Milestones, and Purchased Interest with any officer of Company and with one nationally recognized independent certified public accountant; *provided* that Company and its Affiliates shall not be required to provide such access more frequently than once in any Fiscal Year and, *provided further*, that such action above would not constitute a Confidentiality Breach.

(d) Company shall maintain a system of accounting established and administered in accordance with sound business practices and GAAP.

**Section 1.03 Material Contracts.**

(a) Company shall comply with all material terms and conditions of and fulfill all of its material obligations under all Material Contracts relating to the Royalties, Milestones, and the Purchased Interest (including, without limitation, the License Agreement and Sublicense Agreement). Company shall not amend any such Material Contract or issue any consents or other approvals under any such Material Contract that would have a material adverse effect on the amount, timing, or duration of the payments to be made in respect of the Purchased Interest without the prior written consent of Investor. Company shall, at Investor's expense, take, all actions reasonably necessary to enforce its rights under any such Material Contract (subject to the reasonable direction and approval of Investor) and perform all of its obligations under any such Material Contract.

(b) Termination of Sublicense Agreement.

(i) In the event any Sublicense Agreement is terminated for any reason whatsoever, Company shall, at Investor's expense, use commercially reasonable efforts to locate and secure one or more replacement Sublicensee(s) and enter into a replacement sublicense agreement granting such replacement Sublicensee a license and sublicense under the Intellectual Property to commercialize Xaciato in the Field in the Territory.

(ii) In the event that that the Sublicense Agreement is terminated during the Payment Term, and Company enters into a replacement sublicense agreement in respect of the Xaciato Product, the Purchased Interest shall include, and Investor shall be entitled to, the same percentages of the Net Milestone Payments and Net Royalty Payments set forth in Exhibit D; provided that such Net Milestone Payments and Net Royalty Payments shall be calculated using the royalties and milestones set forth in the new replacement sublicense agreement.

**Section 1.04 Confidentiality; Public Announcement.**

(a) Except as expressly authorized in this Agreement or the other Transaction Documents, and subject to Section 5.02, Investor hereby agrees to (i) use the Confidential Information solely for the purpose of the transactions contemplated by this Agreement and the other Transaction Documents and as necessary in exercising its rights and remedies and performing its obligations hereunder and thereunder; (ii) keep confidential the Confidential Information; (iii) not furnish or disclose to any Person any Confidential Information; (iv) not make use of the trademark, logo, service mark, trade dress or other mark or symbol identifying or associated with the Licensed Products, any manufacturer, distributor or supplier of the Licensed Products, and (v) take the same commercially reasonable steps to protect the Confidential Information as its takes to protect its own proprietary and confidential information. Notwithstanding anything to the contrary set forth in this Agreement, the parties acknowledge and agree that Confidential Information (other than Sublicensee/Licensor Confidential Information) shall not include any information to the extent it can be established by competent written records (A) is, at the time of disclosure, or thereafter becomes, a part of the public domain or publicly known or available, other than through any act or omission of Investor in breach of the obligations under this Section 5.04, (B) was known to Investor at the time of disclosure to Investor, (C) is, at the time of disclosure, or thereafter becomes, known to Investor from a source that had a lawful right to disclose such information to others or (D) was independently developed by Investor without use or reference to any Confidential Information.

(b) Notwithstanding anything to the contrary set forth in this Agreement other than Section 5.04(g), Investor may, without the consent of Company, (i) furnish or disclose Confidential Information of Company (for the avoidance of doubt, other than Sublicensee/Licensor Confidential Information) to its or any of its Affiliates' actual and potential partners, directors, employees, managers, officers, investors, co-investors, financing parties, bankers, lenders, advisors, trustees and representatives ("Representatives") on a need-to-know basis provided that such Persons shall be informed of the confidential nature of such information and such Persons shall be under confidentiality and non-use obligations with respect to such information on terms substantially similar to this Section 5.04 for a period of at least three (3) years following the end of the Payment Term, and (ii) furnish or disclose Confidential Information of Company (for the avoidance of doubt, other than Sublicensee/Licensor Confidential Information) to any potential or actual purchaser, transferee or assignee (including non-Affiliates) of all or any portion of the Purchased Interest to whom Investor is entitled to sell, transfer pledge or assign the Purchased Interest (or portion thereof) under Section 7.05 of this Agreement provided that such potential or actual purchaser, transferee or assignee shall be informed of the confidential nature of such information and such potential or actual purchaser,

transferee or assignee shall be under confidentiality and non-use obligations with respect to such information on terms substantially similar to this Section 5.04 for a period of at least three (3) years following the end of the Payment Term.

(c) In the event that Investor, its Affiliates or their respective Representatives are required by Applicable Law or legal or judicial process (including by deposition, interrogatory, request for documents, subpoena, civil investigative demand or similar process) to furnish or disclose any portion of the Confidential Information of Company (for the avoidance of doubt, other than Sublicensee/Licensor Confidential Information), Investor shall, to the extent legally permitted, provide Company, as promptly as practicable, with written notice of the existence of, and terms and circumstances relating to, such requirement, so that Company may seek a protective order or other appropriate remedy (and, if Company seeks such an order, Investor, such Affiliates or such Representatives, as the case may be, shall provide, at Company's expense, such cooperation as Company shall reasonably require). Subject to the foregoing, Investor, such Affiliates or such Representatives, as the case may be, may disclose that portion (and only that portion) of the Confidential Information Company that is legally required to be disclosed; *provided, however*, that Investor, such Affiliates or such Representatives, as the case may be, shall exercise reasonable efforts (at Company's expense) to obtain reliable assurance that confidential treatment will be accorded any such Confidential Information of Company disclosed.

(d) Notwithstanding anything to the contrary contained in this Agreement, Investor may disclose the Confidential Information of Company (for the avoidance of doubt other than Sublicensee/Licensor Confidential Information), including this Agreement, the other Transaction Documents and the terms and conditions hereof and thereof, to the extent necessary in connection with the enforcement of its rights and remedies hereunder or thereunder or as required to perfect Investor's rights hereunder or thereunder; *provided* that, Investor shall only disclose that portion of such Confidential Information of Company that its counsel advises that it is legally required to disclose and is necessary to disclose to enforce or perfect its rights and remedies hereunder and thereunder, and will exercise commercially reasonable efforts to ensure that confidential treatment will be accorded to that portion of such Confidential Information of Company that is being disclosed, including requesting confidential treatment of information in the Transaction Documents (for purposes of clarity, Investor shall not be required to seek confidential treatment with respect to any financing statements permitted under Section 6.01(b), but the forms of such initial financing statements will be provided to Company for approval prior to filing, which shall not be unreasonably withheld). In any such event, Investor will not oppose action by Company to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded such Confidential Information of Company so disclosed.

(e) In addition, Company consents and agrees that Investor may publicly disclose the transaction contemplated by this Agreement as may be required under Applicable Law, including under the Securities Exchange Act of 1934, as amended, or as may be required under applicable stock exchange rules. Prior to any public disclosure by Investor pursuant to this Section 5.04(e), Investor will provide a draft of the proposed public disclosure to Company for prior approval, which shall not be unreasonably withheld.

(f) Except as set forth below, the Parties' obligations under this Section 5.04 shall remain in effect during the Payment Term and shall continue until the three (3) year anniversary of the end of the Payment Term; *provided*, *however*, that for any and all trade secrets, the Parties' obligations under this Section 5.04 shall remain in effect during the Payment Term and shall continue for so long as such information qualifies as a trade secret under applicable federal and/or state law.

(g) Company and Investor shall agree on the initial public announcement of the transactions contemplated by the Transaction Documents. Company may thereafter make such further public announcement regarding the transactions contemplated by the Transaction Documents as it wishes. Investor shall be permitted to make such further disclosures as is consistent with such initial public announcement or prior public announcements by Company or with Company's prior written consent not to be unreasonably withheld or delayed.

(h) The confidentiality provisions set forth in this Section 5.04 supersede the provisions of the Confidentiality Agreement in all respects, and all Confidential Information disclosed to Investor prior to the Effective Date shall be instead treated as Confidential Information under this Section 5.04. Upon the Effective Date, the Confidentiality Agreement shall immediately terminate and shall have no further force and effect.

**Section 1.05 Further Assurance.**

(a) Subject to the terms and conditions of this Agreement, each of the Parties shall use commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under Applicable Laws and regulations to consummate the transactions contemplated by this Agreement and any other Transaction Document. Each of the Parties agree to execute and deliver such other documents, certificates, agreements and other writings (including any financing statement filings requested by Investor) and to take such other actions as may be reasonably requested by a Party that are reasonably necessary to vest in Investor good, valid and marketable rights and interests in and to the Purchased Interest in accordance with this Agreement and the Transaction Documents, subject and subordinate, in all respects, to all of the rights of the Licensor and Sublicensee under the License Agreement and the Sublicense Agreement.

(b) Each of the Parties shall execute and deliver such additional documents, certificates, and instruments, and to perform such additional acts, as may be reasonably requested and necessary to carry out and effectuate the provisions of this Agreement and any other Transaction Document and to consummate the transactions contemplated by this Agreement and any other Transaction Documents.

(c) Each of the Parties shall cooperate and provide assistance as reasonably requested by the other Parties at such other Parties' expense, in connection with any litigation, arbitration or other proceeding (whether threatened, existing, initiated, or contemplated prior to, on or after the date hereof) to which any Party hereto or any of its officers, directors, shareholders, agents or employees is or may become a Party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interests, in each case relating to this Agreement, any other Transaction Document, the Purchased Interest, or the transactions described herein or therein.

**Section 1.06 [Reserved].**

**Section 1.07 Intellectual Property.**

(a) Subject in all respects to the terms and conditions of the Sublicense Agreement and License Agreement, Company shall, either directly or by causing the Sublicensee to do so, take any actions (including taking legal action to specifically enforce the applicable terms of the License Agreement and the Sublicense Agreement) requested by Investor that are reasonably necessary to (i) diligently prosecute and maintain the applicable Intellectual Property and the Patents in the Field in the Territory and (ii) diligently defend or assert such Intellectual Property and such Patents against infringement or interference by any other Persons in the Field in the Territory, and against any claims of invalidity or unenforceability, in any jurisdiction in the Field

in the Territory (including, without limitation, by bringing any legal action for infringement or defending any counterclaim of invalidity or action of a Third Party for declaratory judgment of non-infringement or non-interference). Company shall keep Investor reasonably informed of all such actions and Investor shall, to the extent permitted under the Sublicense Agreement and License Agreement, have the opportunity to participate and meaningfully consult with Company with respect to the direction thereof. Company shall, in good faith, consider all input from Investor, and, subject to the rights of the Licensor under the License Agreement and Sublicensee under the Sublicense Agreement, if, in Investor's reasonable judgment, Company does not exercise diligent efforts with respect to its rights under the License Agreement or Sublicense Agreement relating to the prosecution or maintenance of the Product Specific Patents, Investor may, in its sole discretion, and only to the extent permitted under the applicable Sublicense Agreement and License Agreement, assume control of the prosecution and maintenance of the Product Specific Patents at Investor's sole cost and expense. Company shall not, and shall use its commercially reasonable efforts to exercise its rights under the Sublicense Agreement and License Agreement to cause the Licensee and Sublicensee to not, disclaim or abandon or fail to take any action necessary to prevent the disclaimer or abandonment of the applicable Patents or other Intellectual Property where such disclaimer or abandonment would be reasonably likely to result in a Material Adverse Effect.

(b) Company shall use commercially reasonable efforts to exercise its rights under the Sublicense Agreement and License Agreement that it may have to prosecute all pending patent applications related to the Licensed Product as listed in Schedule 3.12(a).

(c) Company shall directly take, or subject in all respects to the terms and conditions of the Sublicense Agreement cause Sublicensee to take, any and all actions and prepare, execute, deliver, and file any and all agreements, documents or instruments that are reasonably necessary in order to secure and maintain all Regulatory Approvals. Company may not withdraw or abandon or fail to take any action necessary to prevent the withdrawal or abandonment of any Regulatory Approval once obtained without the prior written consent of Investor.

**Section 1.08 Negative Covenants.**

Subject to Section 5.09, Company may not without the prior written consent of Investor:

(a) forgive, release, delay, postpone or compromise any amount owed to Company in respect of the Royalties and Milestones;

(b) waive, amend, cancel, or terminate, exercise, or fail to exercise, any material rights constituting or relating to the Royalties and Milestones;

(c) amend, modify, restate, cancel, supplement, terminate or waive any provision of the License Agreement or Sublicense Agreement, or grant any consent thereunder, or agree to do any of the foregoing, including, without limitation, entering into any agreement with the Licensor under the provisions of the License Agreement, in each case if such action or waiver would be reasonably likely to have a material adverse effect on the amount, timing, or duration of the payments in respect of the Purchased Interest.

(d) create, incur, assume, or suffer to exist any Lien, or exercise any right of rescission, offset, counterclaim or defense, upon or with respect to the Purchased Interest, or agree to do or suffer to exist any of the foregoing, except for any Lien or agreements in favor of Investor granted under or pursuant to this Agreement and the other Transaction Documents; or

(e) sell, lease, sub license, transfer, or assign (or attempt to do any of the foregoing) all or any portion of the Purchased Interest, other than as permitted hereunder.

**Section 1.09 Future Agreements.**

(a) Notwithstanding anything in this Agreement to the contrary, Company shall have the right directly, or through a wholly owned Affiliate, sell, assign, pledge as security (including by way of a grant of a security interest in), contribute, convey, grants, collaterally assign, or otherwise transfer to a Third Party such portion of the Royalties and Milestones which are not included in the Purchased Interest (together with the Purchased Interest relating thereto).

(b) Notwithstanding anything in this Agreement to the contrary, there shall be no restrictions on Company's ability to grant further licenses and sublicenses to Third Parties with respect to the Products or any other products, and Investor shall enter into a non-disturbance agreement reasonably acceptable to Company with such future licensees and sublicensees subordinating the rights of Investor to the rights of such future licensees and sublicensees.

**Section 1.10 Notice.**

Company shall provide Investor with written notice as promptly as reasonably practicable (and in any event within ten (10) Business Days) after becoming aware of any of the following:

(a) any material breach or default by Company of any covenant, agreement or other provision of this Agreement or any other Transaction Document;

(b) any representation or warranty made or deemed made by Company in any of the Transaction Documents or in any certificate delivered to Investor pursuant hereto shall prove to be untrue, inaccurate, or incomplete in any material respect on the date as of which made or deemed made;

(c) any further sublicense by a Sublicensee of any rights sublicensed pursuant to any Sublicense Agreement;

(d) the occurrence of a Bankruptcy Event with respect to Company, any Licensor, or any Sublicensee; and

(e) any material breach or default by any Licensor under any License Agreement, or the termination of any License Agreement.

**Section 1.11 [Reserved].**

## Article VI.
## EFFECTIVE DATE

Section 1.01 **Effective Date Deliverables.** On the Effective Date:

(a) Warrant. Company shall deliver to Investor the Closing Warrant to purchase 5,000,000 shares of Company Common Stock.

(b) Corporate Documents of Company. Company shall deliver to Investor a certificate of an executive officer of Company to the effect set forth in Exhibit E (the statements made in which shall be true and correct on and as of the Effective Date) together with (A) the certificate of incorporation and by-laws of Company, and all amendments thereto, and (B) resolutions duly adopted by the board of directors of Company (or an authorized committee thereof) authorizing and approving the transactions contemplated hereunder and the execution, delivery and performance of this Agreement and the other Transaction Documents to which it is a party.

(c) Incumbency Certificate of Investor. Investor shall deliver to Company a certificate of an officer of Investor, dated the Effective Date, setting forth the incumbency of the officer or officers of Investor who have executed and delivered the Transaction Documents, including therein a signature specimen of each such officer.

(d) Payment of Initial Investment Amount. Investor shall pay to Company, and Company shall have received, the Initial Investment Amount payment required under Section 2.03(a) of the Agreement.

(e) Tax Forms. Investor will deliver to Company a valid and properly executed IRS Form W-9 certifying that Investor is a U.S. Person that is exempt from United States federal withholding Tax with respect to all payments in respect of the Purchased Interest. Company will deliver to Investor, a valid and properly executed IRS Form W-9 certifying that Company is a U.S. Person that is exempt from United States federal withholding Tax with respect to all payments from Investor to Company.

## Article VII.
## MISCELLANEOUS

**Section 1.01 Termination; Survival.**

(a) This Agreement shall terminate on the date that is the earlier of (i) the date upon which the payment of the Purchased Interest in respect of the Xaciato Product is made in full to Investor pursuant to and in accordance with the terms of the Transaction, and (ii) the payment to Investor of an aggregate amount under this Agreement equal to the Hard Cap.

(b) In the event of the termination of this Agreement, this Agreement shall become void and of no further force and effect, except for those rights and obligations that have accrued prior to the date of such termination, including the payment in accordance with the terms hereof of the Purchased Interest earned prior the date of such termination and there shall be no liability on the part of any Party hereto, any of its Affiliates or controlling Persons or any of their respective officers, directors, shareholders, members, partners, controlling Persons, managers, agents or employees, other than as provided for in this Section 7.01(b). Nothing contained in this Section 7.01 shall relieve any Party hereto from liability for any breach of this Agreement that occurs prior to such termination.

(c) Upon termination of this Agreement in whole or in part, Investor will return or destroy all tangible materials comprising, bearing, or containing any Confidential Information that is in Investor's or its Affiliates' possession or control (or if the Agreement is terminated only with respect to a Product, such Confidential Information that relates to such Product) and provide written certification of such return or destruction.

**Section 1.02 Survival.**

All representations and warranties made herein and in any other Transaction Document, any certificates or in any other writing delivered pursuant hereto or in connection herewith shall survive the execution and delivery of this Agreement and shall continue to survive until the 18 month anniversary of the Effective Date; provided, further, however, that it is understood and agreed that, notwithstanding the survival provisions of this Section 7.02, all of the representations and warranties made by the Parties hereto are made only as of the Effective Date. The obligations of (a) Company to indemnify and hold harmless any Investor Indemnified Party under Section 7.06(a) and (b) Investor to indemnify and hold harmless any Company Indemnified Party under Section 7.06(b), in each case shall terminate (i) when the applicable representation or warranty terminates pursuant to this Section 7.02, with respect to claims made

pursuant to Section 7.06(a)(i) and Section 7.06(b)(i), as applicable, and (ii) 60 days after the expiration of the applicable statute of limitations (or waivers or extensions thereof), with respect to claims made pursuant to Section 7.06(a)(ii) and Section 7.06(b)(ii), Section 7.06(b)(iii), Section 7.06(c) or Section 7.06(d); provided, however, that, in each case, such obligations to indemnify and hold harmless shall not terminate with respect to any item as to which a Investor Indemnified Party or a Company Indemnified Party shall have, before the expiration of the applicable period, previously notified the indemnifying Party pursuant to and in accordance with Section 7.06(c).

**Section 1.03 Specific Performance.**

Each of the Parties hereto acknowledges that the other Party may have no adequate remedy at law if it fails to perform any of its obligations under any of the Transaction Documents. In such event, each of the parties agrees that the other Party shall have the right, in addition to any other rights it may have (whether at law or in equity), to specific performance of this Agreement.

**Section 1.04 Notices.**

All notices, consents, waivers, and communications hereunder given by any party to the other shall be in writing (including facsimile transmission and electronic mail) and delivered personally, by facsimile, by electronic mail, by a recognized overnight courier, or by dispatching the same by certified or registered mail, return receipt requested, with postage prepaid, in each case addressed:

If to Investor to:

United in Endeavour, LLC
1900 The Exchange SE
Suite 480
Atlanta, GA 30339
Attention: E. Adam Webb

If to Company to:

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

with a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
919 Third Avenue
New York, NY 10022
Attention: Richard Gervase, Esq.

or to such other address or addresses as the Parties may from time to time respectively designate by notice as provided herein, except that notices of changes of address shall be effective only upon receipt. All such notices, consents, waivers and communications shall: (a) when posted by certified or registered mail, postage prepaid, return receipt requested, be effective upon delivery,

or if delivery is attempted and refused, upon attempted delivery, (b) when sent by electronic mail, be effective one (1) Business Day after transmission, or (c) when delivered by a recognized overnight courier or in person, be effective upon receipt when hand delivered.

**Section 1.05 Successors and Assigns.**

The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and, subject to this Section 7.05 and the other provisions of this Agreement, their respective successors and permitted assigns. Company shall not be entitled to assign any of its obligations and rights under this Agreement without the prior written consent of Investor, not to be unreasonably withheld, conditioned or delayed, and any such purported assignment, delegation or transfer without such consent will be void ab initio and of no effect; provided, however, such consent shall not be required in connection with a Change of Control of Company. Neither this Agreement nor any of Investor's rights, interests, or obligations hereunder (including Investor's rights in respect of the Purchased Interest) may be assigned, delegated, or otherwise transferred, in whole or in part, by operation of law, merger, change of control, or otherwise by Investor without the prior written consent of Company (such consent not to be unreasonably withheld, conditioned or delayed) and the consent of the Sublicensee and Licensor whose Consent is required, and any such purported assignment, delegation or transfer without any such required consent will be void ab initio and of no effect.

**Section 1.06 Indemnification; Dispute Resolution.**

(a) Company shall defend, indemnify and hold harmless Investor and its Affiliates and any of their respective directors, managers, members, officers, employees and agents (each a "Investor Indemnified Party") from and against any and all Losses incurred or suffered by any Investor Indemnified Party arising out of (i) any breach of any representation, warranty, or certification made by Company in any of the Transaction Documents or certificates given by Company in writing pursuant hereto or thereto, or (ii) any breach of or default under any covenant or agreement by Company pursuant to any Transaction Document, including any failure by Company to satisfy any of the Excluded Liabilities and Obligations to the extent that any such Losses are not caused by Investor and subject to indemnification by Investor hereunder; provided, however, that Company shall not be liable for the payment to any Investor Indemnified Party for any portion of such Losses resulting from such Investor Indemnified Party's gross negligence or willful misconduct. Notwithstanding the foregoing, except to the extent that any Consent is insufficient to allow Investor to receive the Purchased Interest, no Investor Indemnified Party shall be entitled to be indemnified for, or held harmless from, any Losses pursuant to this Section 7.06(a) to the extent such Losses are based on or result from (x) the failure by any Party to obtain a required Consent, or (y) any Consent that is obtained being deficient in any way.

(b) Investor shall defend, indemnify and hold harmless Company and its Affiliates and any of their respective directors, managers, members, officers, employees and agents (each a "Company Indemnified Party") from and against any and all Losses incurred or suffered by any Company Indemnified Party arising out of (i) any breach of any representation, warranty, or certification made by Investor in any of the Transaction Documents or certificates given by Investor in writing pursuant hereto or thereto, (ii) any breach of or default under any covenant or agreement by Investor pursuant to any Transaction Document, and (iii) any claims asserted by any Third Party to the extent based on action taken by Company at the express direction of Investor pursuant to the terms of this Agreement, other than actions which Company would have been obligated to take under the Sublicense Agreement or the License Agreement in order to avoid a breach even if Company had not been so directed by Investor; provided, however, that Investor shall not be liable for the payment to any Company Indemnified Party for any portion of

such Losses resulting from such Company Indemnified Party's gross negligence or willful misconduct.

(c) If any claim, demand, action or proceeding (including any investigation by any Governmental Authority) shall be brought or alleged by a Third Party against an Indemnified Party in respect of which indemnity is to be sought against an indemnifying Party pursuant to the preceding paragraphs (a) or (b) (a "Third Party Claim"), the Indemnified Party shall, promptly after receipt of notice of the commencement of any such claim, demand, action or proceeding, notify the indemnifying Party in writing of the commencement of such claim, demand, action or proceeding, enclosing a copy of all papers served, if any; provided, that the omission to so notify such indemnifying Party will not relieve the indemnifying Party from any liability that it may have to any Indemnified Party under the foregoing provisions of this Section 7.06 unless, and only to the extent that, such omission results in the forfeiture of, or has a material adverse effect on the exercise or prosecution of, substantive rights or defenses by the indemnifying Party. In case any such action is brought against an Indemnified Party and it notifies the indemnifying Party of the commencement thereof, the indemnifying Party will be entitled to participate therein and, to the extent that it may wish, jointly with any other indemnifying Party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such Indemnified Party (who shall not, except with the consent of the Indemnified Party, be counsel to the indemnifying Party), and after notice from the indemnifying Party to such Indemnified Party of its election so to assume the defense thereof, the indemnifying Party will not be liable to such Indemnified Party under this Section 7.06 for any legal or other expenses subsequently incurred by such Indemnified Party in connection with the defense thereof other than reasonable costs of investigation. In any such proceeding, an Indemnified Party shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the expense of such Indemnified Party unless (i) the indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel, (ii) the indemnifying Party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such Indemnified Party or (iii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying Party and the Indemnified Party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them based on the advice of such counsel. It is agreed that the indemnifying Party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm (in addition to local counsel where necessary) for all such Indemnified Parties. The indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent. No indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Party is or could have been a party and indemnity could have been sought hereunder by such Indemnified Party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such proceeding.

(d) Claims for Breach. With the exception of breach of contract claims the indemnification afforded by this Section 7.06 shall be the sole and exclusive remedy for any and all Losses sustained or incurred by an Indemnified Party hereto in connection with the transactions contemplated by the Transaction Documents. With the exception of breach of contract claims the only legal action that may be asserted by or on behalf of any Party with respect to an alleged breach of this Agreement or another Transaction Document or any other matter arising out of the transactions contemplated by this Agreement or another Transaction Document shall be an action to enforce or to recover Losses as an indemnification claim pursuant to this Section 7.06. The Party asserting such a claim shall provide the other Party with written notice setting forth in detail the factual and legal basis for such claim, and the Party against whom such a claim is alleged shall thereafter have 60 days within which to cure the alleged

breach or otherwise remedy the situation. In the event the alleged breach is not cured or the situation is not otherwise remedied within such 60 day period, the non-breaching Party may initiate legal action to enforce its rights under this Agreement or another Transaction Document. Without limiting the generality of the foregoing, with the exception of breach of contract claims, no legal action based upon predecessor or successor liability, contribution, tort, strict liability or any statute, regulation or ordinance may be maintained by or on behalf of any Party or any Indemnified Party with respect to any matter that is the subject of this Section 7.06.

(e) Losses shall be (a) calculated net of actual recoveries received by or on behalf of Indemnified Party under insurance policies, risk sharing pools or similar arrangements (net of any actual collection costs and recoveries and deductibles) and (b) reduced by any proceeds received from third parties, through indemnification, counterclaim or otherwise in compensation for the subject matter of an indemnification claim made hereunder. If any proceeds, benefits or recoveries are received by or on behalf an Indemnified Party with respect to Losses after any indemnifying Party has made an indemnification payment to any Indemnified Party with respect thereto and receipt of such proceeds, benefits or recoveries prior to such payment would have reduced the amount of such indemnification payment if received prior to such payment, then such Indemnified Party shall hold such amounts in trust for the benefit of such indemnifying Party and, within three (3) Business Days after receipt thereof, deliver such amounts (grossed up for any applicable withholding tax) to such indemnifying Party by wire transfer of immediately available funds as directed by such indemnifying Party.

(f) After any final decision, judgment or award with respect to any claim for which indemnification is available under this Section 7.06 and for which Losses have been awarded by a court of competent jurisdiction and the expiration of the time in which to appeal therefrom, the Indemnified Party shall forward to the indemnifying Party notice of any sums due and owing by the indemnifying Party on account of any Claim for indemnification made pursuant to this Agreement with respect to such matter, and the indemnifying Party shall pay all such amounts to the Indemnified Party within ten (10) Business Days of receipt of such notice.

(g) Notwithstanding anything in this Agreement to the contrary, except to the extent actually paid to a Third Party in respect of a Third Party Claim, in no event shall (a) any Party be liable under this Section 7.06 for any indirect, consequential, special or punitive damages or loss of profits, (b) Company and its employees, officers, directors, agents, successors or assigns, taken as a whole, be liable for any Losses in the aggregate greater than (x) the amount of the Purchased Interest when due under this Agreement, less (y) the amount of all payments in respect of the Purchased Interest already received by Investor, and (c) Investor or any of its employees, officers, directors, agents, successors or assigns, taken as a whole, be liable for any Losses in the aggregate greater than the amount of the sum of the Aggregate Investment Amount and each of the Contingent Investment Amount Payments (if any) paid by Investor to Company when due under this Agreement. For clarity, no Party hereto shall have any right to terminate this Agreement or any other Transaction Document as a result of any breach by any other Party hereto hereof or thereof, but instead shall have the rights set forth in this Section 7.06.

(h) The Parties shall use commercially reasonable efforts to cooperate with each other in order to resolve or mitigate any claims indemnifiable under this Section 7.06. Each Party shall respond to any claims in substantially the same manner it would respond to such claims in the absence of the indemnification provisions of this Agreement. If any Party intentionally fails to make such commercially reasonable efforts to mitigate or resolve any such claim, then, notwithstanding anything else to the contrary contained herein, the other Parties shall not be required to indemnify any Person for any portion of such indemnifiable loss that could reasonably be expected to have been avoided if such Party had made such efforts.

(i) Prior to bringing a legal action against the other Party, such dispute shall be separately negotiated by the Parties hereto in good faith and all reasonable efforts undertaken to settle amicably such matters before resorting to further legal recourse, as follows: upon the occurrence of a dispute between the Parties, including, without limitation, any breach of this Agreement or any obligation relating thereto, the matter shall be referred first to the officers of Company and Investor having responsibility for the subject matter of the dispute, or their designees. The officers, or their designees, as the case may be, shall negotiate in good faith to resolve such dispute in a mutually satisfactory manner for up to thirty (30) days. If such efforts do not result in mutually satisfactory resolution of the dispute, the matter shall be referred to the chief executive officers of Company and Investor, or their designees. The chief executive officers, or their designees, as the case may be, shall negotiate in good faith to resolve such dispute in a mutually satisfactory manner for up to thirty additional (30) days, or such longer period of time to which the chief executive officers may agree. In the event the dispute has not been resolved at the end of such thirty (30) day period (or such longer period as agreed to by the chief executive officers of the Parties), either Party shall be entitled to bring an action in accordance with Section 7.06(a) and (b), above.

**Section 1.07 Independent Nature of Relationship.**

The relationship between Company, on the one hand, and Investor, on the other hand, is solely that of assignor and assignee, and neither Investor, on the one hand, nor Company, on the other hand, has any fiduciary or other special relationship with the other or any of their respective Affiliates.

**Section 1.08 Tax.**

(a) The Parties (i) agree that for U.S. federal and applicable state and local income Tax purposes, the transactions contemplated by this Agreement are intended to constitute a debt instrument that is subject to U.S. Treasury Regulations under Section 1.1275-4(b) governing contingent payment debt instruments and (ii) agree that the rights in respect of the Total Investment Amount constitute a debt instrument for U.S. federal and applicable state and local income tax purposes. The Parties agree not to take and to not cause or permit their Affiliates to take, any position that is inconsistent with the provisions of this Section 7.08 on any U.S. federal, state or local income Tax return or for any other U.S. federal, state or local income Tax purpose, unless the Party that contemplates taking such an inconsistent position has been advised by national recognized counsel or accounting firm in writing that it is more likely than not that the inconsistent position is required by applicable Law or unless required by the good faith resolution of a Tax audit or other Tax proceeding.

(b) On or prior to the Effective Date, Investor shall have delivered to Company a valid, properly executed IRS Form W-9 certifying that such Investor is (or payments to such Investor are) exempt from U.S. federal withholding tax with respect to any and all payments pursuant to this Agreement. Investor will notify Company reasonably in advance of any action or proposed action that would make any such form inaccurate and will replace the inaccurate form with an accurate one. Company shall provide the Investor any reasonable assistance it may seek in obtaining an exemption or reduced rate from, or refund of, any U.S. federal withholding tax, if applicable.

Each Party's obligations under this Section 7.08 shall survive the termination of this Agreement, any assignment by Investor and the payment, satisfaction or discharge of all obligations under this Agreement.

(c) The Parties hereto agree not to take any position that is inconsistent with the provisions of this Section 7.08 on any tax return or in any audit or other administrative or judicial

proceeding unless (i) the other Party to this Agreement has consented in writing to such actions, or (ii) the Party that contemplates taking such an inconsistent position has been advised by nationally recognized tax counsel in writing that there is no "reasonable basis" (within the meaning of Treasury Regulation Section 1.6662-3(b)(3)) for the position specified in this Section 7.08. If a Governmental Authority conducts an inquiry of any Party related to this Section 7.08, the Parties hereto shall cooperate with each other in responding to such inquiry in a reasonable manner consistent with this Section 7.08.

(d) This Agreement is not intended to create a deemed partnership, association or joint venture between Investor and Company. Each Party agrees not to refer to the other as a "partner," or the relationship as a "partnership" or "joint venture."

**Section 1.12 Entire Agreement.**

This Agreement, together with the Exhibits and Schedules hereto, and the other Transaction Documents constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements (including the Term Sheet dated December 15, 2023, between Investor and Company), understandings and negotiations, both written and oral, between the Parties with respect to the subject matter of this Agreement. No representation, inducement, promise, understanding, condition, or warranty not set forth herein (or in the Exhibits, Schedules, or other Transaction Documents) has been made or relied upon by either Party hereto. None of this Agreement, nor any provision hereof, is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder.

**Section 1.10 Amendments; No Waivers.**

(a) This Agreement or any term or provision hereof may not be amended, changed, or modified except with the written consent of the Parties hereto. No waiver of any right hereunder shall be effective unless such waiver is signed in writing by the Party against whom such waiver is sought to be enforced.

(b) No failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power, or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

**Section 1.11 Interpretation.**

When a reference is made in this Agreement to Articles, Sections, Schedules or Exhibits, such reference shall be to an Article, Section, Schedule or Exhibit to this Agreement unless otherwise indicated. The words "include," "includes" and "including" when used herein shall be deemed in each case to be followed by the words "without limitation". Neither Party hereto shall be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one party or the other.

**Section 1.12 Headings and Captions.**

The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement.

**Section 1.13 Counterparts; Effectiveness.**

This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement shall become effective when each Party hereto shall have received a counterpart hereof signed by the other Parties hereto. Any counterpart may be executed by facsimile or pdf signature and such facsimile or pdf signature shall be deemed an original.

**Section 1.14 Severability.**

If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions shall nevertheless be given full force and effect.

**Section 1.15 Expenses.**

Each Party hereto will pay all of its own fees and expenses in connection with entering into and consummating the transactions contemplated by this Agreement.

**Section 1.16 Governing Law; Jurisdiction.**

(a) This Agreement shall be governed and construed in accordance with the laws of the State of Georgia, USA, without giving effect to any choice of law provisions thereof. Each Party hereby submits itself for the purpose of this Agreement and any controversy arising hereunder to the exclusive jurisdiction of the state and federal courts located in Cobb County, Georgia, USA, and any courts of appeal therefrom, and waives any objection on the grounds of lack of jurisdiction (including, without limitation, venue) to the exercise of such jurisdiction over it by any such courts.

(b) Each Party hereto hereby irrevocably consents to the service of process out of any of the courts referred to in subsection (a) above of this Section 7.16 in any such suit, action or proceeding by the mailing of copies thereof by registered or certified mail, postage prepaid, to it at its address set forth in this Agreement. Each Party hereto hereby irrevocably waives any objection to such service of process and further irrevocably waives and agrees not to plead or claim in any suit, action or proceeding commenced hereunder or under any other Transaction Document that service of process was in any way invalid or ineffective. Nothing herein shall affect the right of a Party to serve process on the other Party in any other manner permitted by law.

**Section 1.17 Waiver of Jury Trial.**

Each Party hereto hereby irrevocably waives, to the fullest extent permitted by Applicable Law, any and all right to trial by jury in any action, proceeding, claim or counterclaim arising out of or relating to any Transaction Document, or the transactions contemplated under any Transaction Document. This waiver shall apply to any subsequent amendments, renewals, supplements, or modifications to any Transaction Document.

[SIGNATURE PAGE FOLLOWS]

**IN WITNESS WHEREOF,** the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

INVESTOR: UNITED IN ENDEAVOR, LLC

By: /S/ ADAM WEBB
Name: Adam Webb
Title: Managing Member

By: /S/ MARK GREEN
Name: Mark Green
Title: President

COMPANY: DARÉ BIOSCIENCE, INC.

By: /S/ SABRINA JOHNSON
Name: Sabrina Johnson
Title: Chief Executive Officer

**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 |
| Daré MBI Inc. | Delaware |

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-254862 and 333-238299) and Form S-8 (File Nos. 333-264020, 333-266699, 333-254864, 333-237473, 333-230802, 333-226904, 333-211697, 333-204007, and 333-198126) of our report dated March 28, 2024, with respect to our audit of the consolidated financial statements of **Daré Bioscience, Inc. and Subsidiaries (Company)** as of and for the year ended December 31, 2023 (which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern), which report is included in this Annual Report on Form 10-K.

*/s/ Haskell & White, LLP*

San Diego, California
March 28, 2024

**Exhibit 23.2**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-254862 and 333-238299) and Form S-8 (File Nos. 333-264020, 333-266699, 333-254864, 333-237473, 333-230802, 333-226904, 333-211697, 333-204007, and 333-198126) of our report dated March 30, 2023, with respect to our audit of the consolidated financial statements of **Daré Bioscience, Inc. and Subsidiaries (Company)** as of and for the year ended December 31, 2022 (which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern), which report is included in this Annual Report on Form 10-K.

*/s/ Mayer Hoffman McCann P.C.*

San Diego, California
March 28, 2024

**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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. 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 28, 2024

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

**Exhibit 32.1**

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

In connection with the Annual Report on Form 10-K of Daré Bioscience, Inc. (the "Company") for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

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

**Exhibit 97**

**DARÉ BIOSCIENCE, INC.**

**POLICY ON RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION**

**November 17, 2023**[1]

1. **Overview**

The Board believes that it is in the best interests of the Company and its stockholders to adopt this Policy to provide for the recovery of certain Incentive-Based Compensation in the event of an Accounting Restatement. This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, the regulations and rules promulgated by the SEC thereunder, including, without limitation, Rule 10D-1 promulgated under the Exchange Act (" Rule 10D-1"), and the applicable rules, regulations and listing standards of the Exchange (collectively, and as the same may be in effect from time to time, the "Applicable Rules"). Unless otherwise defined in this Policy, capitalized terms used in this Policy have the meanings given to them in Section 2.

2. **Definitions**

(a) "Accounting Restatement" means an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

(b) "Board" means the Board of Directors of the Company, as constituted from time to time.

(c) "Clawback Eligible Incentive-Based Compensation" means, in connection with an Accounting Restatement and with respect to each individual who served as a Senior Executive at any time during the applicable performance period for any Incentive-Based Compensation (whether or not such Senior Executive is serving at the time the Erroneously Awarded Compensation is required to be recouped by the Company), all Incentive-Based Compensation Received by such Senior Executive (i) on or after the Effective Date, (ii) after beginning service as a Senior Executive, (iii) while the Company has a class of securities listed on a national securities exchange, and (iv) during the applicable Look-Back Period.

(d) "Committee" means the Compensation Committee of the Board or such other committee or subcommittee of the Board, if any, duly appointed to administer this Policy and having such powers in each instance as shall be specified by the Board and as specified in Section 3 of this Policy. The Board may also serve as the Committee.

(e) "Company" means Daré Bioscience, Inc., a Delaware corporation.

(f) "Effective Date" means October 2, 2023.

(g) "Erroneously Awarded Compensation" means, with respect to each Senior Executive in connection with an Accounting Restatement, the amount of the Clawback Eligible Incentive-Based Compensation that exceeds the amount of the Incentive-Based Compensation that would have been Received had the amount of such Incentive-Based Compensation been calculated based on the restated amounts, as determined by the Committee, calculated by the Committee without regard to any taxes paid. With respect to Incentive-Based Compensation based on (or derived from) TSR or stock price, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the Committee shall determine the amount of Erroneously Awarded Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the TSR or stock price upon which the Incentive-Based Compensation was Received.

(h) "Exchange" means The Nasdaq Stock Market.

(i) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(j) "Financial Reporting Measure" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure, including but not limited to, "non-GAAP financial measures" for purposes of Exchange Act Regulation G and Item 10 of Regulation S-K, as well as other measures, metrics and ratios that are not non-GAAP measures, like same store sales. Financial Reporting Measures include but are not limited to the following (and any measures derived from the following): stock price; TSR; revenues; net income; operating income; profitability of one or more reportable segments; financial ratios (e.g., accounts receivable turnover and inventory turnover rates); earnings before interest, taxes, depreciation and amortization; funds from operations and adjusted funds from operations; liquidity measures (e.g., working capital, operating cash flow); return measures (e.g., return on invested capital, return on assets); earnings measures (e.g., earnings per share); sales per square foot or same store sales, where sales is subject to an Accounting Restatement; revenue per user, or average revenue per user, where revenue is subject to an Accounting Restatement; cost per employee, where cost is subject to an Accounting Restatement; any of such financial reporting measures relative to a peer group, where the Company's financial reporting measure is subject to an Accounting Restatement; and tax basis income. A Financial Reporting Measure need not be presented within the Company's financial statements or included in a report or other document filed with the SEC.

(k) "Incentive-Based Compensation" means any compensation granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure, measured on a pre-tax basis. Incentive-Based Compensation includes, without limitation: any non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal; bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and stock appreciation rights that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure Performance Goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure performance goal.

(l) "Look-Back Period" means, with respect to an Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period that comprises a period of at least nine months shall count as a completed fiscal year).

(m) "Policy" means this Policy on Recovery of Erroneously Awarded Compensation as the same may be amended, modified, supplemented, and/or restated from time to time.

(n) "Received" means, with respect to Incentive-Based Compensation, actual or deemed receipt, and Incentive-Based Compensation shall be deemed "Received" in the Company's fiscal period during which the applicable Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period. If an equity award vests only upon satisfaction of a Financial Reporting Measure performance condition, the award shall be deemed Received in the fiscal period when it vests. Ministerial acts or other conditions necessary to effect issuance or payment, such as calculating the amount earned or obtaining Board approval of payment, do not affect the determination of the date Received.

(o) "Restatement Date" means the earlier to occur of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement or (ii) the date a court, regulator or other legally authorized

body directs the Company to prepare an Accounting Restatement, in each case regardless of if or when the restated financial statements are filed.

(p) "SEC" means the U.S. Securities and Exchange Commission.

(q) "Senior Executives" means any person who was the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performed a policy-making function, or any other person who performed similar policy-making functions for the Company and any other "key employees" who were designated as "Senior Executives" by the Committee. Executive officers of the Company's parents or subsidiaries may be deemed Senior Executives if they perform policy-making functions for the Company. For purposes of this definition, policy-making function is not intended to include policy-making functions that are not significant. All executive officers of the Company identified by the Board pursuant to Item 401(b) of Regulation S-K shall be deemed Senior Executives.

(r) "TSR" means total stockholder return.

3. **Administration of Policy**

(a) The Policy shall be administrated by the Committee. All questions of interpretation or application of this Policy shall be determined by the Committee. All Committee decisions shall be final and binding upon all persons and shall be afforded the maximum deference permitted under applicable law. The Committee is authorized to make all determinations necessary, appropriate or advisable for the administration of this Policy and to use any of the Company's resources it deems appropriate to recoup Erroneously Awarded Compensation.

(b) Determinations of financial and/or accounting irregularities for purposes of this Policy shall be made by the Committee independently of, and the Committee shall not be bound by, determinations by management or by any other committee of the Board.

(c) In the administration of this Policy, the Committee is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to any limitation under applicable law, the Committee may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

4. **Accounting Restatements; Recoupment**

(a) If the Company is required to prepare an Accounting Restatement, the Company shall determine, in accordance with this Policy and the Applicable Rules, the amount of any Erroneously Awarded Compensation for each Senior Executive in connection with such Accounting Restatement, irrespective of any fault, misconduct or responsibility of any Senior Executive for the Accounting Restatement, and thereafter the Company shall reasonably promptly recover such amount of Erroneously Awarded Compensation. In connection with the foregoing, the Committee, which may act in conjunction with the Company's Audit Committee, shall take all such actions required by this Policy and the Applicable Rules.

(b) If there was Erroneously Awarded Compensation, the Committee shall determine, in its sole discretion, the timing and method(s) for promptly recouping the same, which methods may include, without limitation, one or more of the following: (i) requiring reimbursement of any Erroneously Awarded Compensation; (ii) requiring reimbursement of any equity based compensation awarded; (iii) cancelling outstanding cash or equity-based awards, whether vested or unvested or paid or unpaid; (iv) cancelling or offsetting against any compensation otherwise owed by the Company to the Senior Executive, including any future cash or equity-based awards; (v) requiring the forfeiture of deferred compensation, subject to compliance with Section 409A of

the Internal Revenue Code and the regulations promulgated thereunder; (vi) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards; and (viii) pursuing any other reasonable remedies. Subject to compliance with applicable law, the Committee may effect recoupment under this Policy from any amount otherwise payable to a Senior Executive, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by the Senior Executive.

(c) To the extent that the Committee determines to recoup Erroneously Awarded Compensation from a Senior Executive by requiring the repayment of such Erroneously Awarded Compensation to the Company, and such Senior Executive fails to repay all Erroneously Awarded Compensation to the Company when due, the Company may take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Senior Executive. The applicable Senior Executive shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(d) In the event of an Accounting Restatement, except to the extent permitted by the Applicable Rules, the Committee will generally treat all Senior Executives (including former employees) the same with respect to any actions seeking to recoup Erroneously Awarded Compensation.

5. **Impracticability**

Notwithstanding anything to the contrary herein, the Company shall not be required to recoup Erroneously Awarded Compensation under this Policy if the Compensation Committee of the Board, or in the absence of such a committee, a majority of the independent directors serving on the Board, has determined that recovery would be impracticable in accordance with the Applicable Rules and subject to the procedural and disclosure requirements in the Applicable Rules.

6. **Other Recoupment Rights**

The Board intends that this Policy shall be applied to the fullest extent of the law. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company under applicable law (including, without limitation, Section 304 of the U.S. Sarbanes-Oxley Act of 2002, as amended, or Section 954 of the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as amended), pursuant to the terms of any other policy of the Company, pursuant to the terms of any employment agreement, equity award agreement, severance or other agreement, and any other legal remedies available to the Company. Nothing herein, and no recoupment or recovery as contemplated by this Policy, shall (i) limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Senior Executive arising out of or resulting from any actions or omissions by the Senior Executive or (ii) limit the Company's ability to seek recovery, in appropriate circumstances (including circumstances beyond the scope of this Policy) as permitted by applicable law, of any amounts from any employee, whether or not the employee is a Senior Executive.

7. **No Indemnification or Company-Paid Insurance**

Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Senior Executive that may be interpreted to the contrary: (a) the Company shall not indemnify any Senior Executive against (i) the loss of any Erroneously Awarded Compensation that is recouped, repaid, returned or recovered pursuant to the terms of this Policy; or (ii) any claims relating to the Company's enforcement of its rights under this Policy; and (b) the Company is prohibited from paying or reimbursing a Senior Executive for the cost of or premiums of any third-party insurance purchased to fund any potential obligations of a Senior Executive under this Policy. Further, the Company shall not enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company's right to recoup any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

8. **Committee Indemnification**

No members of the Committee, nor any other members of the Board who assist in the administration of this Policy, nor any officer of employee of the Company authorized and empowered by the Committee who assists in the administration of this Policy shall be personally liable for any action, determination or interpretation made with respect to this Policy, and each of the foregoing shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board or any officer of employee of the Company under applicable law, Company policy or contractual arrangement.

9. **Retroactive Application**

This Policy applies to any Incentive-Based Compensation that is Received by a Senior Executive on or after the Effective Date, even if such Incentive-Based Compensation was approved, awarded, granted or paid to such Senior Executive prior to the Effective Date. Without limiting the generality of Section 4, and subject to applicable law, the Committee may recoup Erroneously Awarded Compensation under this Policy from any amount of compensation approved, awarded, granted, payable or paid to the Senior Executive prior to, on or after the Effective Date.

10. **Notice to Senior Executives**

The Company shall provide notice and seek written agreement to this Policy from each Senior Executive in form attached hereto; provided, that the failure to obtain such agreement shall have no impact on the applicability or enforceability of this Policy.

11. **Amendment and Termination; Interpretation; Successors**

(a) The Board may amend, modify, supplement, restate, rescind, terminate or replace all or any portion of this Policy at any time and from time to time in its sole discretion, including, without limitation, as the Board deems necessary to reflect and comply with applicable law or any of the Applicable Rules. To the extent of any inconsistency between this Policy and any of the Applicable Rules, the Applicable Rules shall control and this Policy shall be deemed amended to incorporate such Applicable Rules unless the Committee shall expressly determine otherwise. Notwithstanding anything to the contrary herein, no amendment, modification, supplement, restatement, rescission, termination or replacement of this Policy shall be effective if such amendment, modification, supplement, restatement, rescission, termination or replacement would (after taking into account any actions taken by the Company contemporaneously with such amendment, modification, supplement, restatement, rescission, termination or replacement) cause the Company to violate any of the Applicable Rules or other applicable law.

(b) This Policy shall be binding and enforceable against all Senior Executives and their beneficiaries, heirs, executors, administrators or other legal representatives, to the fullest extent of the law.

[1] This Policy was adopted by the Board on the date specified.