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, 2025

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 **San Diego, CA** (Address of Principal Executive Offices)	**92122** (Zip Code)

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

Securities registered pursuant to 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 pursuant to 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 ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant 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. ☐

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). ☐

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

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 was approximately $21,339,826 based on the closing price of the registrant's common stock as reported on the Nasdaq Capital Market on such day. 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 25, 2026, there were 14,559,502 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 2026 annual meeting of shareholders (the "2026 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2026 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, 2025
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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 "aim," "goal," "prepare,", "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;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *Inability to generate significant revenue from sales of DARE to PLAY and other potential compounded drugs under Section 503B of the Federal Food, Drug, and Cosmetic Act, or FDCA;*
- *Inability to maintain and enter into arrangements with outsourcing facilities on commercially reasonable terms required to compound and distribute the compounded drugs that we seek to make available under Section 503B of the FDCA;*
- *The removal of sildenafil citrate or any other bulk drug substance needed to compound the compounded drugs that we seek to make available under Section 503B of the FDCA from the FDA's list of bulk drug substances that can be compounded under Section 503B of the FDCA;*
- *The performance of third parties on which we will rely to bring to market, or assist us in bringing to market, compounded drugs;*
- *A change in regulatory requirements related to compounded drugs under Section 503B of the FDCA;*
- *Difficulties or delays in commencement or completion, or the termination or suspension, of our current or planned clinical or preclinical studies;*
- *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 number and scope of product development programs we pursue;*

- *Termination by Organon of our out-license agreement for commercialization of XACIATO® (clindamycin phosphate) vaginal gel 2%, or XACIATO;*
- *The timing and amount of future upside-sharing milestone payments from XOMA under our traditional and synthetic royalty purchase agreements, if any;*
- *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 FDCA, 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, our product candidates, and DARE to PLAY or potential other Section 503B compounded drugs;*
- *The timing and amount of our payment and other obligations under our in-license and acquisition agreements for XACIATO, our product candidates, and DARE to PLAY or potential other Section 503B compounded drugs;*
- *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 grants and other financial awards from governmental entities and private foundations 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;*
- *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 purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions. Every innovation we advance is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, pelvic pain to fertility, vaginal health to infectious disease, we're working to close critical gaps in care using science that serves her needs.

For decades, women have been told to "wait it out" or "live with it," while innovations that could improve their quality of life languish in the regulatory or funding pipeline.

With growing awareness around menopause, sexual health, and vaginal health, the conversation is shifting. However, access to real, evidence-based solutions continues to lag. Daré was founded to change that. As a female-led health biotech company, we are accelerating the development of credible, science-based solutions that meet the

high standards of clinical rigor – randomized, controlled trials; validated endpoints; peer-reviewed publications; and current Good Manufacturing Practice (cGMP) requirements.

We regularly hear from healthcare providers, researchers, and women themselves about the urgent need for expanded access to evidenced-based and convenient options. Our goal is to fulfill that need by bringing innovative products to market as soon as practicable, whether as FDA-approved therapies or through alternative regulatory pathways that enable earlier availability, such as Section 503B compounding. Through a pipeline of investigational products and near-commercial, alternative pathway products, we aim to close persistent gaps in care and deliver clinically meaningful advances that redefine standards in women's health.

In March 2025, we announced an expansion of our business model to include a dual-path approach to bringing new products to market. For select proprietary formulations, we are pursuing both traditional FDA approval and earlier market access via outsourcing facilities registered under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), which may compound and distribute certain drugs without patient-specific prescriptions. We believe this strategy allows us to respond to clinician and patient demand for timely access while continuing to generate the data necessary to seek FDA approval and support long-term value creation. In addition to prescription-based offerings — both FDA-approved products and compounded drugs— we intend to bring to market select consumer health products that do not require a physician's prescription, where appropriate based on product profile and market opportunity, the first of which, as discussed below, will be our DARE to RESTORE™ product offerings.

In December 2025 we initiated commercialization of DARE to PLAY™ Sildenafil Cream, which we also refer to as DARE to PLAY, a first-of-its-kind, topically applied formulation of sildenafil designed to improve female sexual arousal. We believe the product's positioning – science-backed, evidence-driven, and female-focused – sets a new benchmark for credibility in the female sexual wellness category.

The first product in our DARE to RESTORE™ vaginal probiotic suppositories product line, Flora Sync LF5™, is expected to become commercially available in the U.S. in the second quarter of 2026. The products we plan to bring to market under our DARE to RESTORE offerings align with our broader vision to integrate clinically credible, evidence-based products into women's health routines, including select consumer health products.

Our near-term commercial initiatives are designed not only to drive revenue but also to create a self-reinforcing ecosystem for growth. The commercial experience, brand awareness, and provider engagement generated through these products can position us to efficiently introduce additional pipeline candidates, including potential future FDA-approved products. By pursuing a balanced strategy that integrates short-term commercial execution with long-term R&D investment, we aim to reduce reliance on dilutive capital and build a financially sustainable model for innovation in women's health.

We are pursuing a capital-efficient path to commercialization that leverages targeted direct-to-consumer and healthcare professional marketing initiatives to build awareness of our women's health portfolio, including digital campaigns, webinars, social media education, and advocacy programs. We do not have sales, marketing or distribution infrastructure, and currently, we do not intend to build our own sales force or marketing and distribution infrastructure. However, reflecting the shift in our business model, we have been and will be allocating resources to support commercial execution activities, including third-party manufacturing, market preparation, and strategic partnerships.

Prior to 2025, we were solely pursuing traditional FDA approval pathways to market for our product candidates. We began assembling our diverse portfolio of assets in 2017 through acquisitions, exclusive in-licenses and other collaborations. Our portfolio targets product categories we believe represent meaningful opportunities to improve women's health and quality of life. These include contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health, and menopause.

The first FDA-approved product to emerge from our portfolio is XACIATO® (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe). We achieved FDA approval of XACIATO three years after acquiring rights to the program. 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 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. In January 2024, Organon announced that XACIATO was available nationwide in the United States. As described below, to provide funding for the development of the product candidates in our pipeline, in April 2024, we entered into an agreement with XOMA (US) LLC, or XOMA, whereby we sold our rights to all royalty and potential milestone payments based on net sales of XACIATO under our agreement with Organon, net of our obligations to certain third parties, until XOMA receives a

specified return on its investment, after which we will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon.

Our product candidates are in various stages of development, from pre-clinical through a pivotal Phase 3 clinical study. The most advanced product candidates we are developing are: Ovaprene®, an investigational, hormone-free, monthly intravaginal contraceptive currently being evaluated in a pivotal Phase 3 clinical study; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil for the treatment of female sexual arousal disorder (FSAD); DARE-HRT1, an intravaginal ring designed to deliver combination menopausal hormone therapy, bio-identical 17β-estradiol and progesterone together, continuously, over a 28-day period for the treatment of moderate to severe vasomotor symptoms, also known as hot flashes; and DARE-HPV, a proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert being developed as a non-surgical, localized, self-administered therapy for clearance of persistent high-risk human papillomavirus (HPV) infection.

Our Strategy

Our business strategy is to in-license or otherwise acquire the rights to intellectual property and know-how that enables us to develop and bring to market differentiated evidence-based solutions that we believe can address unmet needs in women's health and enhance outcomes and convenience, and that represent compelling and meaningful market opportunities. Certain assets we have in-licensed have existing clinical proof-of-concept data or an established safety profile for the active pharmaceutical ingredient that we seek to leverage. We may pursue regulatory approval of a product candidate through clinical development or, if the active pharmaceutical ingredient is on the FDA's list of bulk drug substances for which there is a clinical need, we may seek to bring it to market under Section 503B of the FDCA. In certain circumstances, as discussed in more detail elsewhere in this "Business" section, we may pursue both pathways. Additionally, our strategy includes bringing Daré-branded non-prescription products to market, representing another pathway to expand our commercial portfolio and offer additional evidence-based solutions to address gaps in women's health. We believe having alternative pathways allows us to bring solutions to market as soon as practicable and optimizes access for women in a fiscally responsible manner.

We are primarily focused on our existing programs. However, we also explore opportunities to expand our portfolio through both business development activities that may result in acquiring, or acquiring access to, new intellectual property rights and know-how 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 will opportunistically explore innovations in women's health that have (a) attractive market opportunities with the potential to address an unmet need, including through new formulations, manners of application or delivery methods of well-characterized drug substances that could result in novel products customized for women, (b) human proof-of-concept clinical data previously generated by third parties, (c) potential to utilize the FDA's 505(b)(2) pathway or be brought to market via Section 503B compounding, and/or (d) potential to become a first-in-category or first-line product. We consider a candidate to have potential to become a "first-in-category" product when we believe that, if the candidate were to successfully complete clinical development and receive FDA marketing approval for the use for which it is being developed, or for which we anticipate developing it, the product would address a need in women's health that is not being met by existing FDA-approved products.

Key elements of our business strategy are as follows:

- *Accelerate innovation in women's health and bring our proprietary formulations and other assets to market as soon as practicable utilizing all available pathways for the asset*, including as a compounded drug under Section 503B of the FDCA, as an FDA-approved product, or as a consumer health product that does not require a physician's prescription.
- *Advance clinical development of the product candidates in our portfolio through mid- to late-stage clinical development or regulatory approval*. In 2025, we continued to make important progress in the clinical development of our product candidates, including with our ongoing pivotal Phase 3 clinical study of Ovaprene.
- *Pursue strategic collaborations to fund our business, enhance our development and commercialization capabilities, and/or commercial offerings, optimizing for access in a fiscally responsible manner.* With respect to our product candidates, 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. With respect to 503B compounding, we intend to develop and maintain relationships with Section 503B-registered outsourcing facilities, dispensing pharmacies, telehealth providers, and other third parties to help bring our proprietary formulations to market. Examples of current strategic collaborations include our license agreement with Organon to commercialize XACIATO, and our arrangements with Bravado Pharmaceuticals, LLC, under which it manufactures DARE to PLAY and fulfills prescription, and Medvantx, a pharmacy services provider, acting as a logistics agent, telehealth platform provider, and dispensing pharmacy for DARE to PLAY.
- *Explore opportunities to expand our portfolio, with evidence-based solutions for 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

portfolio 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.

- *Seek non-dilutive sources of funding to support product development.* We intend to advance development of our product candidates through a variety of means, including through non-dilutive funding and revenue from 503B compounding and non-prescription products. To date, we have received non-dilutive funding from U.S. federal government agencies and/or a private foundation to support various aspects of our research and development activities, from preclinical discovery to a Phase 3 clinical study, for eight of our programs. We intend to continue to explore grants and other forms of non-dilutive funding to support development of our product candidates.

Section 503B Compounding

As discussed above, in March 2025, we announced an expansion of our business model to include bringing to market select proprietary formulations as compounded drug products via Section 503B-registered outsourcing facilities. In assessing which of our proprietary formulations are candidates for Section 503B compounding, in addition to the drug substance(s) being on the FDA's interim 503B Category 1 list of bulk drug substances, we take into account whether we believe the formulation is ready for cGMP manufacturing at scale to meet potential market demand and that the data from nonclinical and clinical studies of the formulation to date will be compelling to healthcare providers. Our 503B compounding products are and will be prescription drug products as required by Section 503B of the FDCA. Section 503B-registered outsourcing facilities must be registered with the FDA, must comply with cGMP requirements, which better ensures quality, strength and consistency of the product, and are subject to FDA inspections. Compounded drugs are not FDA-approved products. The FDA does not evaluate compounded drug products for safety or effectiveness. We do not believe bringing our select proprietary formulations to market via Section 503B compounding will negatively impact the regulatory process or commercial opportunity for an FDA-approved product utilizing the same proprietary formulation.

To execute our Section 503B compounding strategy, among other things, we have entered into and will need to maintain arrangements with one or more FDA-registered Section 503B outsourcing facilities, dispensing pharmacies, telehealth platform providers, and other third parties with marketing, sales or distribution capabilities in the Section 503B market, and we intend to expand our collaborations and vendors as we grow this aspect of our business. We will oversee the overall brand direction for our 503B compounding products , as well as medical education and awareness, including marketing, advertising, and healthcare provider and patient education. We intend to focus our resources on provider-to-provider education about disease states and our proprietary formulations, leveraging online resources, including web-based ordering platforms and collaborations with telehealth platforms and other third parties. We do not have sales, marketing or distribution infrastructure, and currently, we do not intend to build our own sales force or marketing and distribution infrastructure to bring our proprietary formulations to market under Section 503B.

The DARE Health Hub was created as a branded online platform through which healthcare providers can submit prescriptions for our Section 503B compounded drugs, and to support integrated telehealth services and to provide patient-facing order management and communications.

When we use the term "Section 503B," "Section 503B compounding," "503B compounding," or similar terms, we refer to Section 503B of the FDCA and the production and supply of compounded drugs by FDA-registered Section 503B outsourcing facilities without patient-specific prescriptions in accordance with Section 503B of the FDCA. See "Government Regulation—U.S. Government Regulation—Regulation of Compounded Drugs" below for additional information regarding compounding under Section 503B of the FDCA.

DARE to PLAY Sildenafil Cream

Our proprietary topical cream formulation of sildenafil will be our first product to market under Section 503B. As discussed in more detail below, in 2018, we acquired exclusive, worldwide rights to develop and commercialize this formulation for all indications for women related to female sexual dysfunction and/or female reproductive health under a license and collaboration agreement with Strategic Science & Technologies-D LLC and Strategic Science & Technologies, LLC (referred to collectively as SST), and we have completed a Phase 2b clinical study of this formulation that, to our knowledge, was the first clinical trial specifically evaluating a potential therapy for the treatment of female sexual arousal disorder, for which there currently are no FDA-approved products. DARE to PLAY Sildenafil Cream is our branded 503B-compounded drug product utilizing the same formulation of sildenafil citrate evaluated in our completed Phase 2b clinical study. Sildenafil citrate is on the FDA's interim 503B Category 1 list of bulk drug substances that may be used in compounding.

DARE to PLAY, a topically applied formulation of sildenafil, will address an area of women's health that has been historically underserved and stigmatized, and will be a first-of-its-kind product in that, to our knowledge, there are no other topical cream sildenafil products manufactured in accordance with cGMP requirements and supported by clinical data demonstrating increased genital blood flow within 10-15 minutes of application and improvements in arousal sensations using clinically validated and FDA-reviewed endpoints. We believe the product's positioning – science-backed, evidence-driven, and female-focused – sets a new benchmark for credibility in the female sexual wellness category.

The product currently is available for pre-fulfillment, which means that women may complete a telehealth consultation or in-person clinician visit and have a prescription written and held at the dispensing pharmacy, with prescription fulfillment and payment to occur once the product is available for pharmacy dispensing. We expect pharmacy dispensing to commence, and to begin recording revenue from sales of DARE to PLAY, in the second quarter of 2026.

We have entered into an arrangement with a Section 503B-registered outsourcing facility, Bravado Pharmaceuticals, LLC, or Bravado, under which Bravado manufactures DARE to PLAY and fulfills prescription orders through Medvantx, a dispensing pharmacy. Bravado is responsible for obtaining all state-level pharmacy and outsourcing facility licenses required to fulfill DARE to PLAY prescriptions. DARE to PLAY's availability in any given state depends on Bravado's maintenance of the requisite licensure in that state. We have sublicensed our proprietary topical cream formulation of sildenafil to Bravado for use in manufacturing DARE to PLAY.

Medvantx operates the DARE Health Hub and, on behalf of Bravado, verifies and processes healthcare provider-submitted prescriptions for DARE to PLAY. Medvantx also manages patient communications and coordinates with Bravado for the shipment and delivery of fulfilled prescriptions to patients. Medvantx also collects payment from patients at the time of order and, following fulfillment of prescriptions, remits our portion of the revenue to us, after deduction of its fees. Royalties payable to third parties based upon net sales of DARE to PLAY are paid out of the amounts we receive from Medvantx. See "Strategic Agreements for Pipeline Development—SST License and Collaboration Agreement" and "Royalty Monetization Transactions—Traditional and Synthetic Royalty Purchase Agreements with XOMA," below for discussion of such royalties.

DARE to PLAY is currently offered on a cash-pay basis only, and patients pay for the product directly when they place their order. As a compounded drug, DARE to PLAY is not covered by insurance and is not eligible for reimbursement through government or commercial health plans, including Medicare and Medicaid, or under insurance formularies applicable to FDA-approved prescription drug products.

DARE to RECLAIM™ estradiol progesterone intravaginal ring

We are also taking action to bring our proprietary estradiol progesterone intravaginal ring (DARE-HRT1) to market under Section 503B. As discussed in more detail below, in 2018, we acquired exclusive, worldwide rights enabling us to develop and commercialize this product via a license agreement with Catalent JNP (formerly known as Juniper Pharmaceuticals, Inc.), and we have completed Phase 1 and Phase 1/2 clinical studies of DARE-HRT1. The 503B-compounded product will be branded as DARE to RECLAIM estradiol progesterone intravaginal ring, or DARE to RECLAIM. DARE to RECLAIM will utilize the same formulation of bio-identical 17β-estradiol and bio-identical progesterone and intravaginal ring technology evaluated in our completed Phase 1 and Phase 1/2 clinical studies of DARE-HRT1. Each of estradiol and progesterone is on the FDA's interim 503B Category 1 list of bulk drug substances. We are targeting to have DARE to RECLAIM available for prescription fulfillment in early 2027.

DARE to RECLAIM, our intravaginal ring formulation of bioidentical 17β-estradiol and bio-identical progesterone will be a non-oral, monthly hormone therapy. While there are many products on the market targeted to or FDA-approved for the treatment of menopausal symptoms, and both the supplement and compounded hormone therapy markets are very significant, we believe DARE to RECLAIM has the potential to address a preference among some women and healthcare providers for bio-identical hormones delivered in a non-oral route, as well as offer the convenience of an option that is self-administered and does not require daily intervention because each intravaginal ring is meant to be in place for 28 days. There are no FDA-approved products that provide estradiol and progesterone together in a non-oral monthly form, and, to our knowledge, there are no compounded products that provide estradiol and progesterone together in a self-administrable, non-oral, monthly form.

As with DARE to PLAY, we intend to make DARE to RECLAIM available for prescription fulfillment in the United States through a Section 503B registered outsourcing facility, which will not be the same facility that manufactures DARE to PLAY, and Medvantx as the dispensing pharmacy.

We intend to utilize the DARE Health Hub as the commercial platform through which healthcare provider-submitted prescriptions will be verified and processed, and we expect it will be available on a cash-pay basis only, without insurance coverage or third-party payor reimbursement.

Consumer Health Products - DARE to RESTORE

As part of our expanded business model, in addition to 503B compounding, we are working to bring to market in the United States a line of consumer health products branded as the DARE to RESTORE family of products. When we use the term “consumer health products,” we refer to consumer health products that can be obtained without a physician's prescription, because they are all classified as cosmetics.

DARE to RESTORE products will be vaginal probiotic suppositories designed to support vaginal microbiome balance. Our first DARE to RESTORE product, Flora Sync LF5, a vaginal probiotic suppository sourced from Italy, is expected to become commercially available in the U.S. in the second quarter of 2026. The formulation, developed by Probiotical S.p.A. using its proprietary LF5 probiotic strain, is based on scientific research into vaginal microbiome composition and health. Probiotical will manufacture Flora Sync LF5 exclusively for us in the U.S.

Because of the low regulatory barriers to entry, numerous vaginal probiotic products are marketed directly to consumers as dietary supplements or cosmetics. Since no clinical studies or evidence of effect on the vaginal microbiome are required for these products to reach market, most lack strain-specific clinical data. By contrast, Probiotical has invested in research to characterize and clinically evaluate its proprietary LF5 strain, which has been studied in multiple human clinical trials, with findings published in peer-reviewed journals. We believe that level of evidence distinguishes Flora Sync LF5 from the majority of vaginal probiotic products currently available to consumers.

Probiotical has additional proprietary strains and products that align with the objectives of the DARE to RESTORE brand family, and we expect to continue exploring opportunities to expand the DARE to RESTORE commercial offering through additional collaborations with Probiotical.

Similar to our plans with respect to our Section 503B business strategy, we do not have, and currently do not intend to build, our own marketing, sales or distribution infrastructure to commercialize our DARE to RESTORE products, but rather we plan to utilize a capital-efficient path to market that leverages targeted direct-to-consumer and healthcare professional marketing initiatives to build awareness, including digital campaigns, webinars, social media education, and advocacy programs, as well as strategic agreements and collaborations with third parties with marketing, sales or distribution capabilities in the consumer health products market.

We intend to distribute DARE to RESTORE products through the DARE Health Hub, consistent with the commercial infrastructure being built around DARE to PLAY. The dispensing pharmacy's role for DARE to RESTORE product offerings is expected to include online order management, payment processing, and fulfillment logistics, similar to its role in connection with DARE to PLAY, though the absence of a prescription requirement simplifies certain aspects of the fulfillment process for DARE to RESTORE product offerings. We may also pursue additional distribution channels for DARE to RESTORE product offerings, including direct-to-consumer e-commerce and consumer retail.

The DARE to RESTORE vaginal probiotic products are intended to be complementary to our Section 503B prescription offerings. For example, healthcare providers may recommend DARE to RESTORE products in conjunction with DARE to PLAY as part of a comprehensive approach to women's vaginal and sexual health. We intend to build awareness of the DARE to RESTORE products among the consumer and the healthcare provider community that is already engaged with the DARE Health Hub in connection with DARE to PLAY.

XACIATO™

XACIATO (clindamycin phosphate) vaginal gel, a lincosamide antibacterial, received FDA approval in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in female patients 12 years of age and older. XACIATO is our first, and to date, our only product with FDA approval for marketing. We achieved FDA approval of XACIATO three years after acquiring rights to the program. In 2022, we licensed to Organon exclusive worldwide rights to develop, manufacture and commercialize XACIATO. In January 2024, Organon announced that XACIATO was available nationwide in the U.S. See "Organon Exclusive License Agreement," below for further discussion of the terms of our license agreement with Organon.

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) that currently is being evaluated in a pivotal Phase 3 clinical study. Based on the results of our pre-pivotal postcoital test, or PCT, clinical trial, as discussed below, we believe Ovaprene has the potential to achieve “typical use” contraceptive efficacy in the range of approximately 86% to 91% during the first six months of use, which approaches the approximately 93% typical use efficacy rate expected during the first year of use of current FDA-approved non-implanted, non-injected hormonal contraceptive methods (pills, patches and vaginal rings). 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 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.

Ovaprene use did not result in cervicovaginal irritation or adverse effects on resident vaginal microbiota, and did not impact transitions from a Lactobacillus-dominated community state type to an anaerobic, diverse vaginal microbiota community state type IV. Use of Ovaprene resulted in meeting the prespecified criterion for contraceptive effect by all participants during all postcoital test cycles. The safety and PCT results from this study were published in the peer-reviewed journal *Contraception*, an international reproductive health journal and the official journal of the Society for Family Planning.

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. In a peer-reviewed article published in the journal *Biology of Reproduction* that analyzed the use of PCT studies in the development of vaginal contraceptives, the authors observed, for instance, that Lea's Shield and the Ortho and Caya diaphragms had 0 PMS/HPF in their respective PCT studies and six-month typical use failure rates in contraceptive effectiveness trials of 8.7, 7.9, and 12.5%, respectively. The article concluded that, although ultimate contraceptive efficacy is influenced by the ease and convenience of use of a product, along with patient compliance, a PCT study of a test product can be predictive of contraceptive effectiveness, and PCT results similar to results seen with products such as Lea's Shield and the Ortho and Caya diaphragms is the best indicator of likely success of the test product in a contraceptive effectiveness study.

Pivotal Phase 3 Clinical Study

Enrollment is ongoing in our pivotal Phase 3 multi-center, single arm, non-comparative 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 to have approximately 250 participants complete approximately 12 months (13 menstrual cycles) of use. Based on typical dropout rates for contraceptive efficacy studies, we may seek to enroll more than double the number of subjects we target to complete 13 menstrual cycles of use. Participants are being recruited and enrolled at five study sites in the U.S. that were initiated in 2025 with the support of grant funding we received in November 2024. We do not anticipate initiating additional study sites. 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 the submission of a premarket approval application for Ovaprene to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

We currently anticipate enrollment will be completed in 2026, and plan to provide further updates regarding anticipated enrollment and study completion targets in the second half of this year.

In July 2025, the study's data safety monitoring board (DSMB), an independent group of experts which evaluates the safety and integrity of the study, conducted a planned interim analysis and recommended the study continue without modification. No new safety or tolerability concerns were identified. At the time of the interim analysis, approximately 9% of the women treated in the study had experienced a pregnancy. Approximately 17% of participants discontinued the study due to vaginal odor, the most commonly reported product-related adverse event. No serious safety concerns were identified, and overall tolerability was favorable. As of the interim analysis, approximately 115 participants were ongoing or had completed the study. In accordance with the Investigational Device Exemption for Ovaprene, we provided an annual report to the FDA with data collected from the study through September 15, 2025 regarding safety, tolerability and pregnancy experiences. Such data was consistent with the data analyzed by the DSMB during the July 2025 planned interim analysis.

The Phase 3 study is being conducted, in part, under our Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services (HHS), as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development's (NICHD), part of the U.S. National Institutes of Health (NIH). Twenty clinical research sites from within NICHD's Contraceptive Clinical Trials Network (CCTN) were trained on the protocol and were initiated to start screening and enrolling participants in late

2023 and early 2024. In the first quarter of 2025, in connection with the change in U.S. presidential administrations and due to uncertainty regarding the future NICHD budget for the CRADA following U.S. federal policy changes and executive orders, we and NICHD agreed to pause recruitment of new participants at all 15 of the CCTN study sites then following enrolled participants to help ensure the CCTN sites would remain active for continued follow-up with those participants. We will not resume recruitment of participants at the CCTN sites. CCTN sites with ongoing subjects are expected to remain open to complete follow-up visits with those participants. The CRADA will expire in accordance with its terms in July 2026. We do not expect the expiration of the CRADA to have a negative impact on the Phase 3 study. See "Strategic Agreements for Pipeline Development—Cooperative Research and Development Agreement with NICHD, below for additional information regarding the CRADA.

We are collaborating with ADVA-Tec, Inc., or ADVA-Tec, for the development and commercialization of Ovaprene as part of a strategic collaboration announced in March 2017. See "Strategic Agreements for Pipeline Development" below for discussion of the terms of the collaboration.

We previously were also collaborating on Ovaprene with Bayer Healthcare LLC, or Bayer, under a license agreement entered into in January 2020. Under the license agreement, Bayer was supporting the Ovaprene program by providing the equivalent of two experts to advise us in clinical, regulatory, preclinical, commercial, chemistry, manufacturing and controls, and product supply matters, and Bayer had the right to obtain an exclusive license with regard to the commercialization of Ovaprene in the U.S. for human contraception by paying us an additional $20 million fee. We received a notice of termination of the license agreement from Bayer in November 2025, and we agreed with Bayer to terminate the license agreement effective December 2, 2025. Bayer's election to terminate the license agreement was due to its strategic prioritization. We do not expect the termination of the license agreement to have a material impact on the ongoing pivotal Phase 3 study of Ovaprene.

Sildenafil Cream, 3.6%

While numerous pharmaceutical products have been developed and approved to treat erectile dysfunction (ED) in men, women continue to lack effective options for female sexual arousal disorder, or FSAD, which is clinically analogous to ED in men. To date, there are no FDA-approved pharmacological treatments for FSAD. Market research conducted in 2015 suggests that approximately 33% of women in the U.S. ages 21 to 60 are not satisfied with their sexual arousal, and half of those women, 16% of women in the U.S. ages 21 to 60, or approximately 10 million women, are distressed from experiencing symptoms associated with FSAD, including lack of or low sexual arousal, and are actively seeking solutions to improve their condition. In comparison, the prevalence of complete ED in men is estimated to be about 5% of men at age 40, increasing to about 15% at age 70. 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. Because, today, there are no treatments approved by the FDA for FSAD, 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 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. The study enabled us to identify a subgroup of patients who are most likely to benefit from Sildenafil Cream therapy and achieve meaningful improvement in their symptoms.

Based on data from the Phase 2b RESPOND study and feedback from the FDA, we are preparing to advance Sildenafil Cream into a Phase 3 clinical study for the treatment of FSAD. Based on prior communications with the FDA, we currently believe a second confirmatory Phase 3 study will be required to support an NDA submission. 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 conducted by our licensor SST of three escalating doses of topical sildenafil cream (1 g cream with 50 mg sildenafil; 2 g cream with 100 mg sildenafil; and 4 g cream with 200 mg sildenafil) in 20 healthy postmenopausal women using a crossover study design, Sildenafil Cream (then known as SST-6007) demonstrated significantly lower systemic exposure to sildenafil compared to a 100 mg oral sildenafil dose administered to men in a separate clinical study, and was well tolerated at clinically relevant doses (1-2 g cream). Study subjects reported favorable product characteristics: easy to use and readily absorbed. Specifically, the geometric mean maximum plasma concentration of sildenafil in the postmenopausal women in the Phase 1 stucy, after exposure to the 200 mg dose, was 5,262 pg/mL compared to the maximum plasma concentration of sildenafil of 450,000 pg/ML, after exposure to a 100 mg oral dose administered to men in the separate clinical study. Therefore, systemic exposure after the administration of topical sildenafil to postmenopausal women was almost two orders of magnitude lower than seen with oral administration in that separate study. All treatment emergent adverse events were mild, with the most common event being headache, followed by a mild genital burning sensation with product application.

In a Phase 2a, single center, single-dose, double-blind, placebo-controlled, 2-way crossover study conducted by SST, women with FSAD, ages 21 to 60, received a single 2 g dose of Sildenafil Cream (then known as SST 6007). Of the 35 women enrolled, 31 (15 premenopausal and 16 postmenopausal) completed the study. The co-primary objectives were (1) to evaluate the preliminary efficacy of Sildenafil Cream compared to placebo cream in women with FSAD assessed by participant-reported levels of subjective sexual arousal measured continuously by the Arousometer, and (2) to evaluate the effect of Sildenafil Cream compared to a placebo cream on physiological genital response in women with FSAD assessed using the vaginal photoplethysmography amplitude (VPP) and by physiological genital arousal response. Each participant was randomized to the order of use of the placebo cream and Sildenafil Cream in a cross over design. There was a 4-8 day washout between treatments. For each treatment, participants had Arousometer and VPP data collected while viewing a 3-minute neutral, non-erotic film. After the neutral film, the study product was applied and after 5-11 minutes, the participant viewed a 6-minute erotic film with collection of Arousometer and VPP data. There were two different 6-minute erotic films so that the participant did not view the same erotic film with both study product treatments. The VPP data was used to calculate vaginal pulse amplitude (VPA) as a more objective measure of arousal. For the intent to treat population, there was no significant difference in the VPA while viewing the erotic film when participants used Sildenafil Cream versus when they used placebo cream. There was also no significant differences in the VPA when the per protocol population was analyzed by menopausal status (pre versus postmenopausal). Similarly, for the subjective arousal response, measured by the Arousometer, for the intent to treat population, the Arousometer scores were similar when patients viewed the erotic film using Sildenafil Cream versus when they viewed the other erotic film using placebo cream. The results remained not significant when the data was analyzed based on the per protocol population or by menopausal status. Treatment with a single dose of 2 grams of Sildenafil Cream (71 mg sildenafil) applied intravaginally and externally to the labia minora and clitoris in study participants was well tolerated. No serious adverse events (SAEs) were reported. A total of 18 treatment emergent adverse events (TEAEs) were reported, with a similar incidence under Sildenafil Cream treatment (8 events in 4 participants [12.1%]) and under placebo treatment (10 events in 4 participants [12.1%]). The majority of these TEAEs were considered to be related to treatment (14 out of 18). All TEAEs were all mild or moderate in severity; in particular, TEAEs reported under Sildenafil Cream treatment were all mild. Half of the 18 TEAEs reported were in the system organ classification of “Reproductive system and breast disorders”, and events included vaginismus, vulvovaginal burning sensation, vulvovaginal discomfort, and vulvovaginal pain. There were more of these TEAEs under Sildenafil Cream treatment than under placebo (6 and 3, respectively). However, these events were typically transient (lasting less than 1 minute) and resolved without medical attention.

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. One postmenopausal subject had a mild vaginal burning sensation following application of both the placebo cream and Sildenafil Cream, which resolved itself and did not require any additional intervention or study withdrawal. One subject had a small laceration to the perineum post coitus, which was unrelated to study treatment and participation, resolved itself, and did not require additional intervention or withdrawal.

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 well tolerated in the study. Among the 13 enrolled participants, two subjects had a mild vaginal burning sensation following application of Sildenafil Cream and placebo cream. One subject had a mild vaginal burning sensation following application of Sildenafil Cream and placebo cream, which resolved itself and did not require any additional intervention or study withdrawal. Three subjects withdrew from the study for asymptomatic orthostatic tachycardia that occurred during the multiple serial blood draws for pharmacokinetics and one subject withdrew due to bacterial vaginosis. Among the 13 enrolled subjects, ten had adequate paired plasma samples from all three treatments to evaluate. Plasma PK of sildenafil following a single topical (applied externally to the pre-specified vulvar area and internally intravaginally) administration of Sildenafil Cream was characterized and findings were similar to those reported in a prior Phase 1 PK study conducted by our licensor SST.

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 2024, several peer-reviewed journal articles were published on the study, including efficacy findings in *Obstetrics & Gynecology* (2024 Aug 144(2):p 144-152), the official journal of the American College of Obstetricians and Gynecologists (ACOG), and safety findings in *The Journal of Sexual Medicine* (2024 Sep 3;21(9):793-799), the official journal of the International Society for the Study of Women's Sexual Health (ISSWHS). In February 2024, we presented additional findings from the study at the Annual Meeting of ISSWHS. In addition, efficacy findings from the study were the featured topic of ACOG Green Room Gynecology Podcast in August 2024.

During the multi-center, double-blind, randomized, placebo-controlled study (ClinicalTrials.gov ID: NCT04948151), 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. A total of 174 participants completed the study (Sildenafil Cream, n=90, placebo cream, n=84). The study did not meet its co-primary or secondary endpoints, which were measured based on the ITT population. Among the ITT population, which included women with only FSAD as well as those with FSAD and concomitant sexual dysfunction diagnoses or genital pain, though the Sildenafil Cream group demonstrated greater improvement in the Sexual Function Questionnaire (SFQ28) Arousal Sensation (AS) Domain scores, there were no statistically significant differences between Sildenafil Cream and placebo cream users in the co-primary and secondary efficacy endpoints. An exploratory post-hoc subset of the ITT population with an enrollment diagnosis of FSAD with or without concomitant decreased desire randomized to Sildenafil Cream reported significant increases in their SFQ28 AS Domain score (LS Mean [SE] 2.03 [0.62]) compared to placebo cream (LS Mean [SE] 0.08 [0.71]), p=0.04. This subset achieved a larger mean improvement in the SFQ28 Desire and Orgasm Domain scores. This subset population also had significantly reduced sexual distress and interpersonal difficulties with Sildenafil Cream use, as measured by Female Sexual Distress Scale-Desire, Arousal, Orgasm (FSDS-DAO) questions 3, 5, and 10 (all p values≤0.04). In summary, Sildenafil Cream improved outcomes among women with FSAD, most significantly in those who did not have concomitant orgasmic dysfunction. In particular, in an exploratory analysis of a subset of women with FSAD with or without concomitant decreased desire, Sildenafil Cream increased sexual arousal sensation, desire, and orgasm and reduced sexual distress.

During the 12-week double-blind dosing period, there were 78 TEAEs reported by 29 of the 99 Sildenafil Cream-assigned participants and 65 TEAEs reported by 28 of the 94 placebo cream-assigned participants (p=0.76). All TEAEs were mild or moderate in severity. The most common treatment-related TEAE among these participants was application site discomfort. There were no differences in the number of treatment-related TEAEs among Sildenafil Cream versus placebo cream users (p>0.99). Four Sildenafil Cream participants and three placebo cream participants

discontinued the study due to TEAEs involving application site discomfort (p>0.99). There were 9 TEAEs reported by 7 of 91 sexual partners exposed to Sildenafil Cream versus 4 TEAEs reported by 4 of 84 sexual partners exposed to placebo cream (p=0.54). These data demonstrate that Sildenafil Cream was well tolerated by exposed users and their sexual partners.

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-only FSAD 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.

In December 2024, we announced plans for a Phase 3 study of Sildenafil Cream reflecting further FDA feedback for safety and efficacy evaluations to support the indication of treatment of FSAD in premenopausal women. Consistent with the Phase 2b RESPOND study, the planned Phase 3 study will include a 12-week, double-blind treatment period evaluating Sildenafil Cream compared to placebo cream in patients with FSAD with or without concomitant decreased desire. The currently planned Phase 3 study will have co-primary efficacy endpoints- one assessing arousal sensations and one assessing associated distress. The SFQ28 Arousal Sensation Domain endpoint used in the Phase 2b RESPOND study will also be used in the planned Phase 3 study. The question used to assess distress is anticipated to be from the same FSDS-DAO questionnaire used in the Phase 2b RESPOND study, but may be a different question about interpersonal difficulty. In addition, secondary efficacy endpoints to assess improvement in orgasm, desire, and distress and interpersonal difficulties will be included in the Phase 3 study, as they were in the Phase 2b RESPOND study. Based on prior communications with the FDA, we currently believe a second confirmatory Phase 3 study will be required to support an NDA submission.

In April 2025, we received additional input and information requests from the FDA regarding our patient reported outcomes (PRO) psychometrics for the Phase 3 study. The PRO psychometrics analysis has bearing on efficacy endpoint selection and the statistical analysis plan for the Phase 3 study. We submitted additional requested information to the FDA in the second quarter of 2025 related to the FSDS-DAO questions. Pending additional feedback from the FDA, the timing of which is uncertain, and alignment with the FDA on the protocol and statistical analysis plan, we cannot determine whether our prior estimate of capital required to conduct the Phase 3 studies is appropriate. We do not plan to conduct the Phase 3 study until after we achieve alignment with the FDA on the protocol and statistical analysis plan and secure the capital required to conduct the Phase 3 study based on such protocol and statistical analysis plan. We do not anticipate initiating the first Phase 3 study in 2026 and cannot at this time reasonably predict when the study will commence.

We are developing Sildenafil Cream with 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, or GSM, 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 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 conducted by our wholly owned subsidiary in Australia 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” (30(4):p 427-436, April 2023). 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 SAEs 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 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 released E2 in systemic concentrations, which were in the low, normal premenopausal early folicular range and that systemic P4 concentrations were all in the normal post ovulatory range, which predicts endometrial protection. All TEAEs 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-HPV

DARE-HPV (formerly referred to as R-131-2 and DARE-CIN) 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 genital human papillomavirus (HPV) infection in women as well as 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. Essentially all cervical cancers worldwide are caused by infection with one of 14 carcinogenic, or “high-risk” HPV types. While HPV vaccination continues to be a key tool, we believe HPV treatments will also continue to be a key pillar in cervical cancer prevention due to suboptimal vaccine uptake and because the vaccine doesn’t cover all strains of high-risk HPV. While most HPV infections resolve spontaneously, millions of women experience persistent high-risk HPV infection. There is no FDA-approved treatment for HPV infection and no non-surgical pharmaceutical intervention to treat CIN2 or CIN3 (collectively referred to as CIN2+). Today, the standard of care does not treat the virus. Instead, women with persistent high-risk HPV infection are monitored through repeated screening. Intervention typically occurs only after late-stage cervical lesions develop, often requiring surgical procedures such as excisional or ablative treatments of cervical tissue. Current surgical procedures to treat cervical dysplasia are invasive and can adversely impact future pregnancies. We believe a non-surgical, self-administered localized pharmaceutical approach that targets the virus itself rather than waiting for cellular changes to develop has the potential to redefine the treatment paradigm in cervical disease prevention.

In October 2024, we announced that we were selected by the Advanced Research Projects Agency for Health (ARPA-H), part of HHS, to receive up to $10 million in milestone-based payments over approximately two years to support the development of DARE-HPV, including commencement of a Phase 2 clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for the clearance of high-risk HPV infection in women. For more information about this funding, see Note 15, “Grant Awards," to our consolidated financial statements included in this report. To date, we have received $7.5 million of the ARPA-H award.

In February 2026, we announced FDA clearance of our IND application for a Phase 2 clinical study of DARE-HPV to evaluate the safety and antiviral activity of DARE-HPV in women with persistent high-risk HPV infection. The planned Phase 2 study is expected to be supported by ARPA-H award funding. We will provide additional details regarding the Phase 2 study design and anticipated timelines for study initiation, which we are preparing for 2026, in the coming months.

Clinical Data

An earlier non-optimized formulation of the same two active pharmaceutical ingredients in DARE-HPV was previously evaluated in 23 non-pregnant, healthy, premenopausal, HIV un-infected Kenyan women with CIN2 or CIN3 in an open-label, proof-of-concept clinical study with all women receiving a 4:1 (133 mg lopinavir and 33 mg ritonavir) oral tablet (Lopimune) which is FDA approved for the treatment of human immunodeficiency virus (HIV), but dosed vaginally twice daily for 14 days in this study. There were no SAEs. The most common TEAEs were headache (3/23, 13%) followed by vaginal irritation (2/23, 8.7%); nausea (2/23, 8.7%); feeling faint/dizziness (2/23, 8.7%), abnormal vaginal discharge (2/23 8.7%); and abdominal pains (1/23 4.3%). In total, 5/23 or 21.7% of study subjects experienced some form of minor complaint within the first month of taking Lopimune as described. The results demonstrated its potential as a self-applied therapy for HPV infection and related cervical lesions. The proof-of-concept study is published in the Public Library of Science (PLoS) One. DARE-HPV was also previously evaluated in 12 healthy, non-pregnant, premenopausal women without high-risk HPV or CIN. Participants inserted one tablet vaginally daily for 21 days. Participants reported the amount of vaginal or vulvar irritation they experienced daily using a Likert scale ranging from 0 (none) to 1 (mild, does not require medical attention) to 2 (moderate, requires medical attention) to 3 (severe, requires medical attention and results in study medication being stopped). The mean daily vaginal irritation score was 1.47 ± 1.29 for active product users (n=8) versus 1.40 ± 0.9 for placebo product users (n=4).

We are developing DARE-HPV under our license agreement with Douglas Pharmaceuticals, Limited. 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 in a soft gelatin capsule 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 GSM (formerly called vulvar and vaginal atrophy or vulvovaginal atrophy (VVA)). 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 at the tissue level 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 and atrophy. GSM 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. GSM 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 GSM 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 GSM 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 moderate-to-severe dyspareunia, a symptom of GSM .

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 conducting activities in preparation for a Phase 2 randomized, double-blinded, placebo-controlled, dose-finding clinical study of DARE-VVA1 for moderate-to-severe dyspareunia. 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. We do not plan to conduct the Phase 2 study until after we secure additional capital.

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* (2019, 46(2), 285-288) 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. Overall, the study drug was well tolerated. The primary efficacy endpoints evaluated normalization of vaginal pH and improvement of vaginal dryness. Vaginal pH and dryness scores using a visual analog scale were recorded at enrollment and subsequent assessments were recorded using self-assessment questionnaires over a three-month period. Both vaginal pH and vaginal dryness symptoms showed significant improvement after three months compared to baseline, with an approximately 30% improvement in vaginal pH scores and an approximately 63% improvement in vaginal dryness scores. The secondary endpoint was the measurement of tamoxifen concentrations after eight weeks of vaginal tamoxifen administration. 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. 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 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.

Data from the study 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” (2023, 26(5), 479-488). The article concluded that DARE-VVA1 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. Of the 15 participants who reported at least one TEAE, nine reported a TEAE related to the reproductive system, with vulvovaginal discomfort (n=5 participant reports) and vulvovaginal pruritus (n=4 participants reports) being the most common organ system preferred term. The mean local erythema scores for all visits, for all dosing groups, were in the none\absent (0) to mild (1) range, with a few outliers in the moderate (2) grading, with no discernible pattern or correlation to group. All endometrial width measurements assessed with transvaginal ultrasound were normal at baseline and at 57 days of treatment, with the maximum measurement not exceeding 4.0 mm. 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). Plasma tamoxifen concentrations were significantly and negatively correlated with vaginal pH (Spearman $R = -0.51$, $p<0.01$) and % vaginal parabasal cells (Spearman $R = -0.53$, $p<0.01$). Plasma tamoxifen concentrations were significantly and positively correlated with % vaginal superficial cells (Spearman $R = 0.45$, $p<0.01$), % vaginal intermediate cells (Spearman $R = 0.45$, $p <0.01$) and total vaginal maturation index (VMI) (Spearman $R = 0.62$, $p<0.01$). 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 and related license agreements.

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 (the same technology utilized for XACIATO) 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.

Participants received 1% diclofenac (n=14), 3% diclofenac (n=14) or placebo (n=14). All 42 participants completed the nine study visits. The data indicate that the study treatment was well-tolerated, and TEAE profiles were comparable between the DARE-PDM1 treatment groups and the placebo group. There were no differences in the

frequency of reported TEAEs (P=0.41) or treatment related TEAEs (P=0.13) between the 1% and 3% diclofenac strengths, and placebo groups. All TEAEs were mild or moderate in severity. No SAEs were reported, and no TEAEs led to study drug discontinuation or study discontinuation. There were two adverse drug reactions in the 1% diclofenac strength group which included mild vomiting and a mild burning sensation in the lower abdomen. There was a slightly higher frequency of TEAEs reported by participants in the 1% and 3% diclofenac strength groups compared to participants in the placebo group; these were not statistically significant. Three participants (21.4%) and four participants (28.6%) in the 1% and 3% diclofenac strength groups, respectively, reported a total of nine treatment related TEAEs. Gastrointestinal symptoms were the most common treatment related TEAE. Eight of the nine total treatment related TEAEs reported during the study were considered to be mild in severity. One participant in the 3% diclofenac strength group experienced a moderate treatment related TEAE of nausea.

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 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 utilized for DARE-HRT1 and DARE to RECLAIM. We are conducting development activities to support IND submissions and Phase 1 clinical studies of these product candidates. We have a Small Business Innovation Research (SBIR) grant award from the NIH to support a Phase 1 study of DARE-PTB1, but 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.

Casea S

Casea S is an investigational biodegradable contraceptive implant. Casea S is designed to control release of a well-characterized contraceptive, etonogestrel, for a set period of time (18-24 months) before dissolving. It is designed to provide women with a long-acting, minimally-invasive contraceptive method that will not require surgical removal by a healthcare provider, which would improve convenience and could eliminate one of the barriers to use associated with existing implanted contraceptives. Casea S is being tested in a single-center, two-part Phase 1 clinical study to evaluate the PK of etonogestrel, removability, safety, and tolerability of Casea S pellets inserted subdermally in healthy women of reproductive age (ClinicalTrials.gov ID: NCT05174884). The ongoing Phase 1 study is being conducted by FHI 360, a nonprofit organization, with support from a grant award. There are no development costs to us at this time.

In February 2025, we entered into a co-development and licensing agreement with Theramex for the development of Casea S in the U.S. If we determine that the results from the Phase 1 study are positive and elect to proceed with development, we would be responsible for conducting a Phase 2 study in the U.S., In accordance with our agreement, the costs of such Phase 2 study would be shared by us and Theramex on terms to be agreed upon, taking into account the size of the opportunity for Casea S in our respective markets. 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 include:

- **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-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 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 $41.8 million under the grant agreement, the term of which was recently extended to December 31, 2027. Additional payments are contingent upon the DARE-LARC1 program's achievement of development and reporting milestones specified in the grant agreement.

We refer to the technology underlying DARE-LARC1 as our intelligent drug delivery system, or DARE-IDDS, platform. We believe DARE-IDDS has broad potential application beyond contraception in therapeutic areas that currently rely on frequent injections or daily oral dosing, and we are exploring strategic collaboration discussions to expand evaluation of DARE-IDDS for uses outside of reproductive health.

Sales and Marketing

We do not have established marketing, sales or distribution infrastructure or capabilities. In order to commercialize any of our product candidates that would be a new drug, medical device, or drug-device combination product if approved for commercial sale by the FDA or comparable foreign regulatory authorities, 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 preclinical and clinical 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, which has established marketing, sales and distribution capabilities for prescription products in women's health, has global commercial rights to XACIATO under our exclusive license agreement. 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 below for a discussion of the terms of our exclusive out-license agreement with Organon.

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, Organon is responsible for the manufacture and distribution of XACIATO.

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.

For Phase 3 clinical development of Sildenafil Cream and, if approved, for marketing and sale, currently, we plan to obtain clinical supplies from a single source CMO.

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 Pipeline Development

The following is a summary of certain rights and obligations under our strategic agreements and describes expenses incurred during 2025 and our future payment or potential future payment obligations thereunder.

Theramex Co-Development and License Agreement

In February 2025, we entered into a co-development and licensing agreement with Theramex for an investigational biodegradable contraceptive implant called Casea S recently acquired by Theramex. Under the

agreement, we received a royalty-free, exclusive, fully paid up, sublicensable license to the U.S. patents Theramex recently acquired for Casea S. We paid a minimal fee to Theramex in connection with entering into the agreement. There are no development costs to us at this time. If we determine that the results from the ongoing Phase 1 clinical study are positive and elect to proceed with development, we would be responsible for conducting a Phase 2 study in the U.S. In accordance with our agreement, the costs of such Phase 2 study, and the costs of a future Phase 3 study in the U.S., would be shared by us and Theramex on terms to be agreed upon, taking into account the size of the opportunity for Casea S in our respective markets. If we do not elect to proceed with development after reviewing the results from the Phase 1 study, we may terminate the agreement upon notice to Theramex.

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-HPV 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. 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, all of which had been paid as of September 30, 2024. Unless earlier terminated, the CRADA will expire in accordance with its terms in July 2026. 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.

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 and an enhanced version of the drug delivery technology underlying DARE-LARC1 is now known as our intelligent drug delivery system platform, DARE-IDDS.

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 with MBI, $75,000 of the amount payable was paid in cash and the balance was paid in shares of our common stock.

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 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.

Under the terms of the 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.

Under the terms of the Assignment Agreement, as amended:

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

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.

Organon Exclusive License Agreement

In 2022, we entered into an exclusive license agreement with Organon, 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 us. Organon has all manufacturing, regulatory, and compliance responsibilities for XACIATO and is also responsible for commercializing, promoting, determining pricing, and negotiating reimbursement matters related to XACIATO

Under the terms of our license agreement, as amended, Organon agreed to pay tiered double-digit royalties based on net sales and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments are 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.

In April 2024, we sold to XOMA our rights to all royalty and potential milestone payments based on net sales of XACIATO under our license agreement with Organon, net of our obligations to certain third parties, until XOMA receives a specified return on its investment, after which we will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon. See below under "Royalty Monetization Transactions" for additional information.

Unless terminated earlier, our license agreement with Organon 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.

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

Royalty Monetization Transactions

Traditional and Synthetic Royalty Purchase Agreements with XOMA

In April 2024, we entered into a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (which, together, we refer to as the Royalty Purchase Agreements), and XOMA paid $22.0 million to us. In addition, if XOMA receives total payments under the Royalty Purchase Agreements (as described below) equal to an amount that exceeds $88.0 million (which we refer to as the Revenue Sharing Threshold), XOMA will pay $11.0 million to us for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements (such $11.0 million payments to us we refer to as the Contingent Purchase Price Payments).

Under the Royalty Purchase Agreements, we sold, assigned, transferred and conveyed our right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments we would otherwise have the right to receive from and after April 1, 2024 under our exclusive license agreement with Organon, based on net sales of XACIATO, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of us under our exclusive license agreement with third-party licensors TriLogic and MilanaPharm, and (ii) all payments due and payable and actually paid by or on behalf of us under our royalty interest financing agreement with United in Endeavour, LLC, or UiE (such net amount we refer to as the Purchased Receivables);

(b) 25% of the $20.0 million payment that we could have potentially received under our since terminated license agreement with Bayer relating to Ovaprene; and

(c) a synthetic royalty of 4.0% of our, our affiliates' and our sublicensees' future net sales of Ovaprene, and 2.0% of our, our affiliates' and our sublicensees' future net sales of Sildenafil Cream; *provided, however*, that, if XOMA receives total payments under the Royalty Purchase Agreements, net of any Contingent Purchase Price Payments made to us, equal to an amount that exceeds $110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (we refer to the amounts described in this clause (c) as the Revenue Participation Right).

Pursuant to the traditional royalty purchase agreement, XOMA, at its sole cost and discretion, may repay in full and retire all of our payment obligations to UiE under our royalty interest financing agreement with UiE. If XOMA does so, no further amounts in respect of that agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the traditional royalty purchase agreement. Under the traditional royalty purchase agreement, we cannot elect to receive any additional funding from UiE under our royalty interest financing agreement with UiE without XOMA's prior written consent.

In connection with the synthetic royalty purchase agreement, we granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream.

The Royalty Purchase Agreements contain certain representations and warranties regarding our rights and obligations with respect to our license agreement with Organon and our in-license agreements relating to XACIATO, Ovaprene and Sildenafil Cream, as well as customary representations and warranties for a transaction of this nature. The Royalty Purchase Agreements also contain customary covenants for a transaction of this nature, including covenants that limit or restrict our ability to incur indebtedness or liens related to the Purchased Receivables, the Revenue Participation Right, and certain product assets related to Ovaprene and Sildenafil Cream (except pursuant to a suitable intercreditor agreement). The Royalty Purchase Agreements do not restrict our ability to out-license any of our products or product candidates.

Royalty Interest Financing Agreement

In December 2023, we entered into a royalty interest financing agreement with United in Endeavour, LLC, or UiE, pursuant to which we sold to UiE 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 UiE. 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.

Under the agreement, we agreed to make the following payments to UiE until such time when UiE 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: (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 UiE to the extent UiE has not received payments equaling the IRR by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if UiE has not received payments equaling the IRR 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 UiE quarterly payments evenly divided over a two-year term (such payments referred to as Catch-up Payments), such that UiE will have obtained the IRR, taking into account all other payments received by UiE from us under the agreement. UiE's right to receive payments will terminate when UiE has received

payments in an amount equal to the IRR (such period of time referred to as the Financing Term). Under the agreement, we have the right, at any time and from time to time, to make voluntary prepayments to UiE, and such payments will be credited against the IRR. In addition, we have the right at any time to pay in full and retire all of our payment obligations to UiE by paying the full amount of the IRR, calculated as of the date of the payment.

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 UiE, and (ii) the payment to UiE of an aggregate amount equal to the IRR.

In connection with the agreement, we issued to UiE a warrant to purchase up to 422,804 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 84,561 shares of our common stock, for an aggregate of additional warrants to purchase up to 591,927 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 $4.10 per share, subject to customary adjustment for stock splits and similar transactions. 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 four issued U.S. patents, two of which are set to expire in December 2028 and two of which are set to expire in September 2036, subject to any extensions or disclaimers, and two 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 three foreign patents, including one EPO patent validated in 22 countries, that expire in July 2036, subject to any extensions or disclaimers. Two of the four issued U.S. patents are 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 two 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 U.S. application and 16 pending foreign applications regarding XACIATO, and a pending U.S. and five pending foreign applications 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 four granted U.S. patents, one pending U.S. patent application, seven granted foreign patents, including two EPO patents validated in a total of 36 countries, and two 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 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 28 issued patents worldwide (11 U.S. patents and 17 foreign patents, including three EPO patents validated in a total of 20 countries). Additionally, there is one patent application pending in the US, one in Europe, and three 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. Additionally, relative to the sildenafil program, we are the sole owner one patent application pending in the U.S., one in Europe, and five in other international markets with an expected term, if granted, until 2044, subject to any 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 one issued U.S. patent with patent terms set to expire in September 2027, including patent term adjustment. Additionally, relative to the DARE-HRT1 program, we are the sole owner of one patent application pending in the U.S., one in Europe, and eight in other international markets 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 patent application pending in the U.S., one in Europe, and one in Canada 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 10 U.S. patents and 35 foreign patents, including four EPO patents validated in various European countries, and 13 pending patent applications. We believe that the five 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, 2040, and 2046 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 six issued U.S. patents and four foreign patents, as well as two pending U.S. applications and seven pending foreign applications. The U.S. patents are set to expire in 2026, 2028, 2033 and 2034 including any patent term adjustment, extensions or disclaimers, and the foreign patents have patent terms until 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 five granted U.S. patents and four pending U.S. patent applications. The granted patents are expected to expire in 2034, 2039, or 2042, 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 own trademark applications and registrations in the United States Patent & Trademark Office for the DARÉ BIOSCIENCE mark, as well as marks related to various taglines, product candidate and product names, including DARE to PLAY, DARE to RESTORE, and DARE to RECLAIM. According to our agreement with Organon, all XACIATO trademarks have been assigned. In accordance with the terms of the ADVA-Tec license agreement, we are the exclusive licensee of the OVAPRENE registered trademark.

Competition

We are solely focused on women's health. Women's health is a broad category that encompasses health conditions that are unique to women, as well as conditions that affect both men and women, but that may affect women differently. Women's health products include drug, medical device, cosmetic and dietary supplement products, and generally are products designed for post-pubescent females. The women's health sector is very fragmented, highly competitive and subject to rapid and significant change. We anticipate that our products and, if approved, our product candidates may compete not only with FDA-approved, prescription and over-the-counter, branded and generic drug products, but also compounded drug products, medical devices, dietary supplements, and cosmetics. We face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies and specialty pharmaceutical companies that already possess a significant share of the women's health market, as well as generics manufacturers, compounding pharmacies and other drug compounding facilities, and cosmetics and dietary supplements manufacturers. In addition, academic and other research institutions are and could be engaged in research and development efforts for products in the therapeutic areas targeted by our product candidates. Our success is highly dependent upon our ability to acquire or in-license, develop and obtain regulatory approval for innovative products on a cost-effective basis and to market them successfully, either on our own or together with strategic partners, or to make our proprietary formulations available as compounded drugs. 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 Products We Develop" and "Risks Related to 503B Compounding" below.

XACIATO competes 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. As a result of our exclusive license agreement with Organon, the commercial success of XACIATO is 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 intrauterine devices (IUDs), spermicides and vaginal gels, as well as hormonal products such as pills, patches, vaginal rings, IUDs, implantable rods 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. However, Sildenafil Cream, if approved, may compete directly with compounded drugs available in the market, including those from outsourcing facilities that compound topical cream formulations of sildenafil citrate, the active ingredient in Sildenafil Cream. In addition, some compounding entities have partnered with telemedicine providers, enabling them to expand the potential market for their compounded drugs. While, as of the filing date of this report, to our knowledge, DARE to PLAY will be the only compounded form of sildenafil citrate that has completed toxicology studies and Phase 1 and Phase 2 human clinical studies, the availability of other sildenafil products, could potentially make it more challenging for DARE to PLAY and, in the future, if approved by the FDA, Sildenafil Cream, to build and maintain market share.

If we are successful in bringing DARE to RECLAIM, or DARE-HRT1 to market, these products will compete with the many products on the market targeted to 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 supplied by compounding entities, as well as non-hormonal products, including FDA-approved medications Veozah® (fezolinetant) marketed by Astellas Pharma and Lynkuet® (elinzanetant) marketed by Bayer, and dietary supplements. Both the supplement and the compounded hormone therapy markets are very significant. A considerable segment of the compounded hormone therapy market is comprised of compounded hormones in pellet form that are implanted under the skin as a non-daily alternative, which could be directly competitive with DARE to RECLAIM and, in the future, if approved by the FDA, DARE-HRT1. We expect the options for hormone therapy and non -hormonal therapies to continue to expand with time. We intend for DARE-HRT1, if approved by the FDA, to offer advantages to currently available compounded hormone therapy products, including by providing a product with a well characterized safety and efficacy profile that will have been vetted by the FDA. We believe DARE to RECLAIM and DARE-HRT1 each 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 together over 28 days without any daily intervention.

DARE-VVA1, if approved as a treatment for moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of GSM, will compete with other hormonal and non-hormonal products for the treatment of dyspareunia or other GSM symptoms. Such products include hormone therapies in the form of pills, patches and creams, some of which are FDA-approved products and others which are supplied by compounding entities, as well as non-hormonal products in the form of pills and vaginal inserts, such as FDA-approved Osphena® (ospemifene) oral tablet, which is a SERM, and Intrarosa® (prasterone) vaginal insert, which is a steroid. We believe that DARE-VVA1 has the potential to address a preference due to personal or medical reasons among some women and healthcare providers to avoid estrogen and/or treatments with active ingredients that are estrogen-like or can metabolize into estrogen.

Currently, there are no FDA-approved therapies for HPV-related cervical disease. DARE-HPV has the potential to be the first FDA-approved product for the treatment of genital HPV infection in women and/or CIN (also known as cervical dysplasia). Persistent HPV infections can progress to cervical cancer through a series of cervical lesions. Currently, there are no FDA-approved therapeutic treatments for HPV infections and no non-surgical pharmaceutical intervention to treat CIN2+. Surgical procedures are performed to remove late-stage cervical lesions to prevent the development of cervical cancer. We are aware of other product candidates in development to treat HPV-related cervical diseases, including an investigational vaginal insert being developed by Antiva Biosciences as a topical treatment for high-grade cervical intraepithelial neoplasia (HSIL, CIN2+) and for high-risk HPV infection, which currently is being evaluated in two Phase 1/2 clinical trials. These candidates may complete development, achieve FDA approval and be marketed in the U.S. before DARE-HPV, potentially creating direct market competition for DARE-HPV, if approved.

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 or compounded drugs 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, changes in 503B compounding regulations, whether the drug substances in our proprietary formulations appear and remain on the FDA's list of bulk drug substances that may be used in 503B compounding, the actual and perceived efficacy and safety of our products or our proprietary formulations made available via 503B compounding (alone and relative to other treatment options), the degree of patent or other protection afforded to particular products, and coverage and reimbursement by third-party payors.

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 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 amended the FDCA in 2022 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. 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.

In February 2026, via an editorial published the *New England Journal of Medicine*, the FDA Commissioner and the director of the FDA's Center for Biologics Evaluation and Research announced a policy shift whereby, going forward, the FDA's default position will be a "a one-trial requirement," meaning that one adequate and well-controlled study, combined with confirmatory evidence, will serve as the basis of marketing authorization of novel product candidates. Confirmatory evidence can include mechanistic science, data from a related indication, animal models, information from other drugs of the same class, real-world evidence, or a second adequate and well-controlled study. The announcement represents a major shift from the FDA's historical default requirement of two pivotal clinical trials. However, as indicated by FDA representatives during informal interviews and other media appearances, if FDA shifts to only requiring a single trial, it may heighten the standard for these trials in terms of quality. For example, the FDA indicated it will carefully examine all aspects of study design with particular focus on controls, end points, effect size, and statistical protocols. The FDA may still require additional adequate and well-controlled studies if a product candidate has a nebulous, pluripotent, or nonspecific mechanism of action; if it affects a labile, short-term, or surrogate outcome; or if a trial has some underlying limitation or deficiency. The editorial also referenced a new

postmarket initiative being rolled out synchronously to collect robust data on all drugs and devices. The FDA has not published formal guidance regarding the new one-trial default option or postmarket surveillance initiative.

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. Congress is required to re-authorize the agency's user fee programs every five years, and current legislative provisions supporting the PDUFA program are set to expire on September 30, 2027.

Under the current PDUFA goals and policies agreed to by the FDA, the agency 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 nonclinical 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. In September 2025, the FDA began publishing CRLs soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing CRLs with approval documentation after the product is approved. 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, priority review designation, and the Commissioner's National Priority Voucher pilot program. 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, or 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.

Under the Generating Antibiotics Incentives Now Act, or the GAIN Act, Congress directed the FDA to implement the 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.

Additionally, 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.

In 2025, the FDA created a new voucher program called the Commissioners National Priority Voucher, or CNPV, with the goal of radically expediting therapeutic product review and approval processes. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is issued within one to two months after the filing date.

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, none of these programs changes 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. As noted above, in February 2026, the FDA announced a new postmarket data-collection initiative applicable to all drugs and devices, but the FDA has not yet published guidance specific to this new program.

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. The Drug Supply Chain Security Act, or DSCSA, was enacted in 2013 to, among other things, require use of an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates resource-intensive obligations for pharmaceutical manufacturers, repackagers, wholesale distributors, and dispensers (primarily pharmacies). 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. Most recently, the FDA announced trading partner-specific exemptions through specified dates in 2025, 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 Management System Regulation, or QMSR; 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. Notably, the QMSR was developed and implemented to harmonize the FDA's previous medical device current good manufacturing practice regulations (referred to as the Quality System Regulation, or QSR) with the International Organization for Standardization, or ISO, standard for device quality management systems (ISO 13485:2016); it became effective on February 2, 2026.

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 QMSR. 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 an alternative 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. Today, as a result of certain amendments to the FDCA, manufacturers may request *De Novo* classification from the FDA without first submitting a

510(k) premarket notification 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* request, however, the most recent FDA premarket review goals state that in fiscal year 2026, FDA will attempt to issue a decision on 80% 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 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 QMSR, 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;
- correction 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 comprising 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 components;
- 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 updated to reflect its new use as part of the combination; 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, provides sponsors with a prompt determination of the FDA Center with primary jurisdiction over a combination product; ensures timely and effective premarket review by coordinating reviews involving more than one center; ensures consistent and appropriate post-market regulation; resolves disputes regarding review timeliness; and reviews/revises agreements, guidance and practices specific to 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 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 user fee.

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 QMSR 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 QMSR, 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, amended the FDCA to clarify 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. Patents for drug-device combination products that are listed in the Orange Book have recently come under scrutiny by the Federal Trade Commission, and the controversy regarding the appropriateness of listing such patents has led to numerous lawsuits alleging anticompetitive conduct by biopharmaceutical companies.

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.

Other U.S. Health Care Laws and Compliance Requirements

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 as well as prescription drug products that are being manufactured and distributed by 503B outsourcing facilities. 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. Recent U.S. federal actions include initiatives incorporating "most favored nation" (international reference pricing) concepts for certain prescription drugs, as well as agency testing of new payment models that could tie Medicare reimbursement or manufacturer rebates to prices in specified reference countries. For example, 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, CMS is negotiating drug prices annually for a select number of single source Part D drugs without generic competition. CMS is also negotiating 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, announcing the first round of negotiated "maximum fair prices" for the first 10 drugs in August 2024, which became effective as of January 1, 2026 (payment year 2026). The second round of negotiated prices for 15 drug products was announced in November 2025, and CMS published the next group of drugs selected for negotiation in January 2026. 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. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of January 2026, the Trump Administration had secured deals with 16 major drug manufacturers to offer certain drugs at most-favored-nation prices.

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 has led 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, and published interim reports with its findings in mid-2024 and January 2025, that also appear to be contributing to additional federal and state legislative and regulatory proposals, as well as enforcement action and private litigation, targeting such entities’ operations, pharmacy networks, and financial arrangements. In February 2026, President Trump signed into law several PBM regulatory reforms as part of a federal budget package. The Department of Labor (DOL) also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under the Employment Retirement Income Act (ERISA). If finalized as proposed, the DOL rule would also allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. Additional proposals and legislative changes aimed at PBMs and their business practices are likely to continue to be introduced and considered in Congress and by executive agencies. 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 contained 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.

Federal Regulation of Compounded Drugs

Drug compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a customized medication.

Compounded drugs are regulated at the federal level primarily under Section 503A and Section 503B of the FDCA. The FDA does not evaluate compounded drug products for safety, effectiveness, or quality, although it does have oversight over the compounding pharmacies and outsourcing facilities producing such drugs in compliance with the conditions of Section 503A and 503B, respectively.

As discussed above, we are making our proprietary sildenafil cream formulation available to patients by prescription as a compounded drug under the brand name DARE to PLAY Sildenafil Cream via an outsourcing facility operating under Section 503B, and we plan to make our proprietary estradiol progesterone intravaginal ring available to patients by prescription as a compounded drug under the brand name DARE to RECLAIM™ estradiol progesterone intravaginal ring via another outsourcing facility operating under Section 503B.

The term “outsourcing facility” refers to a facility that produces compounded drugs in accordance with Section 503B and distributes them either pursuant to a patient-specific prescription or in response to an order from a health care provider, such as a hospital, that is not for an identified individual patient (e.g., for office stock). Outsourcing facilities must be registered with the FDA and are subject to cGMP requirements and FDA inspections. In addition, an outsourcing facility must meet other conditions described in Section 503B, including reporting adverse events, labeling compounded products with certain information, reporting specific information about the drugs that it compounds, including a list of all of drugs it compounded during the previous six months and the FDA-registered source of the active ingredients used to compound. Under Section 503B, outsourcing facilities are prohibited from selling compounded drugs through a wholesale distributor, subject to certain exceptions set forth in FDA guidance.

Outsourcing facilities may only compound using bulk drug substances that either appear on a list established by the FDA of bulk drug substances for which there is a clinical need or are for drug products on FDA's Drug Shortage List. Although the FDA has not yet finalized its list of bulk drug substances for which there is a clinical need, the FDA has announced an interim policy pursuant to which bulk drug substances may be nominated for inclusion on such list and, provided certain conditions are met, outsourcing facilities may compound with such bulk drug substances pending evaluation of the substances for inclusion on the FDA’s list of bulk drug substances for which there is a clinical need. Each of sildenafil citrate, estradiol, and progesterone as a bulk drug substance that is a component of FDA-approved drugs, is currently listed in FDA's interim Category 1 List of bulk substances that have been nominated, reviewed by FDA, and may be compounded by outsourcing facilities pending FDA’s final evaluation. FDA does not intend to take action against an outsourcing facility for compounding drugs using bulk drug substances

classified as Category 1 substances provided that the conditions described in the agency's January 2025 interim enforcement policy are met.

Under Section 503B, outsourcing facilities are prohibited from compounding a drug that is “essentially a copy” of an FDA-approved drug, unless the drug is on the FDA’s Drug Shortage List at the time of compounding, distribution, and dispensing. A drug is essentially a copy of an FDA-approved drug if it is identical or nearly identical to the FDA-approved drug, which the FDA has interpreted to mean that it has the same active ingredient(s), route of administration, dosage form, dosage strength and excipients as the approved drug, or if it has the same active ingredient as an approved drug and there is not a change from the approved drug that produces a clinical difference for an individual patient, as determined by the prescribing practitioner.

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, 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. Numerous other states have either enacted or are considering enacting their own privacy laws similar to the CCPA.

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.

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.

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.

Notably, the European Commission issued a proposal in 2023 to revise and replace the existing general pharmaceutical legislation for the EU. As of January 2026, the three EU institutions, the European Commission, the European Parliament and the Council of the EU, are in the process of negotiating the final content of the new Directive and Regulation. Once negotiations are complete, the European Parliament and the Council of the EU will vote on whether to approve the Directive and Regulation. If adopted and implemented, these revisions will significantly change several aspects of drug development and approval in the European Union.

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 the MDR, which provided three years for transition and compliance, for a final effective date of May 26, 2020. A further transition period was provided until May 26, 2024 to give 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.

As a new market entrant, we must acquire any necessary device 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 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 previously raised by the Court of Justice of the European Union, or the CJEU, in *a* decision that invalidated the former EU-U.S. Privacy Shield. 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 25, 2026, we had 24 employees. Of those 24 employees, 21 were full-time and three were part-time, and 17 were in research and development and seven were in selling, general and administrative. Our approach is to engage consultants with experience in varying specialties to help us develop our diverse portfolio of product candidates and bring to market 503B compounded products and consumer health products. 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. Our 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, due to our current inability to use a Form S-3 "shelf" registration statement for primary offerings.
- There is no assurance that we will continue to satisfy the listing requirements of the Nasdaq Capital Market. Until July 24, 2026, we are subject to a Nasdaq discretionary panel monitor. If we fail to maintain compliance with any continued listing requirement in Nasdaq's Listing Rules through July 24, 2026, Nasdaq will issue a delist determination letter, and we will have an opportunity to request a new hearing with Nasdaq's hearing panel. Based on information currently available to us, our stockholders' equity is expected to be below the $2.5 million threshold as of March 31, 2026, which, if not remedied prior to the time our quarterly report for the first quarter is filed with the SEC, is expected to result in Nasdaq issuing a delist determination letter, with no guarantee that a subsequent hearing before Nasdaq's hearings panel would result in a favorable outcome. The delisting of our common stock or the commencement of delisting proceedings could materially impair our ability to raise capital and limit financing and business opportunities.
- We have a limited operating history, a history of significant losses from operations, and expect significant losses from operations, net losses and negative cash flows from operations to continue for the foreseeable future, which, together with our limited financial resources, make it difficult to assess our prospects.
- We plan to generate revenue from sales of DARE to PLAY and other potential compounded drugs under Section 503B of the FDCA. We have limited experience in this line of business and may not succeed in our efforts. We rely on, and will rely on, third parties for the compounding and distribution of DARE to PLAY and other potential compounded drugs, and the failure of such third parties to perform as expected could harm our reputation and negatively impact our ability to succeed. In addition, this line of business subjects us to additional regulations and potential liability.
- 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.
- We rely on in-license agreements with third parties for rights to develop and commercialize XACIATO, our product candidates, and DARE to PLAY and other potential compounded drugs. The loss or impairment of our rights under these agreements could disrupt or require us to discontinue development or commercialization activities, or impair our rights to receive payments from our sublicensees, which could have a material adverse effect on our operations and business prospects and viability.
- Strategic collaborations are a key part of our strategy and our existing strategic collaboration related to XACIATO is important to our business. If we are unable to maintain our existing strategic collaboration or establish new ones, or if they are not successful, we may require substantial additional capital to develop and commercialize XACIATO and our product candidates, and our business and prospects may be materially harmed.

- Delays and disruptions in the supply and manufacturing of our product candidates 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.
- 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 commercial success of XACIATO is outside of our control and will depend on Organon's efforts and capabilities, and if commercialization of XACIATO is not successful, our reputation, business and prospects may suffer.
- Our product candidates, if approved for commercial sale, will face intense competition 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 Organon fail to compete effectively.
- Failure to successfully obtain and maintain 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 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.
- If we and our licensors are unable to obtain and maintain sufficient intellectual property protection, competitors could develop, market, commercialize or make available products similar or identical to ours, which could significantly limit the commercial potential of our products and product candidates and materially harm our business, financial condition, results of operations, and prospects.
- Most of the products we are developing utilize active pharmaceutical ingredients that are not proprietary to us or our licensors and the patents and patent applications owned by us and our licensors intended to protect our products and product candidates relate to specific formulations, processes, methods of delivery, and/or uses, which may not afford sufficient protection against competitors.
- Volatility in the financial markets, geopolitical conflicts and events, natural disasters, public health emergencies , international trade policies, 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.
- Future dilution to our existing stockholders from sales and issuances of our common stock to raise additional capital, or the market's expectation that such sales may occur, could adversely affect our stock price even if our business is doing well.
- 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 or confidential 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 significant losses from operations, net losses and negative cash flows from operations for at least the next several years as we develop and seek to bring to market 503B compounded drugs and our product candidates and as we seek to potentially acquire or license and develop additional product candidates. At December 31, 2025, we had an accumulated deficit of approximately $188.7 million, cash and cash equivalents of approximately $24.7 million, and working capital of approximately $3.4 million. Our cash and cash equivalents at December 31, 2025 included funds received under grant agreements that generally may be applied solely toward direct costs for the funded project under those grant agreements other than an approximately 5% to 22% indirect cost allowance, and as of December 31, 2025, our deferred grant funding liability was approximately $19.7 million, substantially all of which consisted of funds intended to support the DARE-LARC1 program, the Ovaprene Phase 3 clinical study, and the DARE-HPV program. We will need additional capital to fund our operating needs through the fourth quarter of 2026 and to meet our current obligations as they become due. These circumstances raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements included in this report 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. Advancing our investigational 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.

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 503B compounded drug offerings and/or our product development programs; relinquish rights under our license agreements with third parties relating to our 503B compounded drug offerings and/or our product candidates; forgo opportunities to expand our 503B compounded drug offerings and/or our product portfolio; take other measures to reduce our expenses; reorganize or merge with another entity; or file for bankruptcy or cease operations. For example, in recent years, due to our limited capital resources, we have focused our resources primarily on the advancement of Ovaprene and Sildenafil Cream, unless a program has been supported by grant or other non-dilutive funding, and we have delayed R&D activities for other programs. 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 503B compounded drug offerings and/or product development programs we choose to pursue;
- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our product candidates that we are pursuing or may choose to pursue in the future;
- the cost and timing of manufacturing for 503B compounded drugs;
- the cost and timing of manufacturing for clinical supplies of product candidates and, if applicable, commercial product at sufficient scale;
- the cost and timing of regulatory submissions to and the timing and outcome of 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 product;
- the amount and timing of future royalty, milestone or other payments, if any, we receive under any future out-licensing agreement or the Royalty Purchase Agreements;
- our ability to maintain, and establish new, strategic collaborations relating to the development and/or commercialization of our product and product candidates, and the terms and timing of such arrangements;
- 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 503B business strategy and/or product development efforts succeed, we will need to develop and implement a commercialization plan for each 503B compounded drug and/or 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 royalty monetization transactions should not be viewed as any 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, rising interest rates, public health emergencies, geopolitical conflict (such as the wars in Ukraine and the Middle East), natural/environmental disasters, supply-chain disruptions, terrorist attacks, strained trade and other 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 forego part or all of potentially valuable streams of future payments (e.g., milestone and/or royalty revenue) to raise immediate capital to fund our operations and advance our development programs, such as in the case of our royalty interest financing agreement and the Royalty Purchase Agreements. 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, a history of significant losses from operations, and expect significant losses from operations, net losses and negative cash flows from operations to continue for the foreseeable future, which, together with our limited financial resources, 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 any products we develop. Other than XACIATO, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue. We have not been profitable since we commenced operations and may never achieve profitability. We 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. We have a history of 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.

The Revenue Sharing Threshold may never be achieved and, as a result, we may not realize any future income based on sales of XACIATO.

We have sold our right, title and interest in 100% of the royalties and potential milestone payments we would otherwise have the right to receive under our license agreement with Organon based on net sales of XACIATO, net of payments to upstream third-party licensors and UiE. Whether we receive any future income based on net sales of XACIATO will depend on whether the Revenue Sharing Threshold is reached, which may not occur. Whether the Revenue Sharing Threshold is reached will depend, in part, on Organon's future commercial success with XACIATO, which is outside of our control and which to date has not resulted in a material amount of net sales, and the successful development and commercialization of Ovaprene and/or Sildenafil Cream, which are subject to significant risks and uncertainties, some of which are outside of our control, as discussed elsewhere in this Risk Factors section.

To the extent we enter into licensing agreements for third-party commercialization of products we develop, as is the case with XACIATO, we expect our revenue streams related to those products will be based primarily on net sales, which will be largely outside of our control.

In a typical biopharmaceutical licensing or "partnering" deal, the biopharmaceutical company out-licenses technology and other assets to a third party in exchange for future payments, the bulk of which (e.g., royalties and milestones) are conditional on the licensee successfully developing and/or commercializing the licensed assets and

determined based on net sales. To the extent we enter into such licensing agreements, the amount of net sales our products may generate, if approved for commercial sale, will be largely outside of our control because marketing and sales activities will be conducted by the licensee and product pricing and costs that impact net sales will be determined by the licensee. Gross sales can be greatly reduced by sales discounts and allowances, which will be determined by our licensee (or mandated by governmental entities). 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 the royalties payable to us and delay potential achievement of commercial milestones and the corresponding milestone payments to us. If a licensee has no or limited commercialization success, or net sales are otherwise minimal due to pricing and discount structures, our financial condition and operating results could be negatively impacted and our need for additional capital could significantly increase or be accelerated. Due to our exclusive license agreements with Organon, our royalty interest financing agreement, and the Royalty Purchase Agreements, XACIATO's value to us will be based primarily on net sales, as determined under those agreements.

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, debt or other structured financings that could be dilutive to our stockholders or involve restrictive covenants, operational restrictions, security interests in our assets, and/or relinquishing part or all of our rights to potentially valuable future revenue streams;
- 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.

If our commercial collaborator terminates its exclusive license agreement with us, our need for additional capital may significantly increase.

We have an exclusive license agreement with Organon for the commercialization of XACIATO. That license agreement may be terminated by Organon for convenience upon the completion of a specified notice period, subject to limited restrictions. If Organon determines to terminate the exclusive license agreement with us, 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 establish another commercial collaboration, which we may not be able to do on a timely basis, on favorable terms, or at all. For example, we had an exclusive license agreement with Bayer for the commercialization of Ovaprene. As discussed elsewhere in this report, we received a notice of termination of the license agreement from Bayer in November 2025, and we agreed with Bayer to terminate the license agreement effective December 2, 2025. If Ovaprene were to receive marketing approval from the FDA, we will need to enter into an agreement with a third party to commercialize Ovaprene, for which no assurances can be given, and if we do not enter into such agreement, the commercialization of Ovaprene would be delayed. See also the risk factor titled, "Our existing product development and commercialization collaboration is important to our business, and future collaborations may also be important to us. If we are unable to maintain our existing collaboration, if it is not successful, or if we are unable to establish additional strategic collaborations, our business and prospects may be materially harmed," below.

We have relied heavily on sales of our common stock to fund our operations, and our 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 $21.3 million in in gross proceeds during 2025, and approximately $93.0 million in gross proceeds since January 1, 2021, 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. Based on the aggregate market value of securities sold by us or on our behalf pursuant to Instruction I.B.6. of Form S-3 in 2025, we do not expect to sell any shares pursuant to Instruction I.B.6. of Form S-3, including under our ATM sales agreement, during the approximately 12-month period from July 2025, unless and until our public float exceeds approximately $54.0 million, as determined in accordance with SEC rules. While 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 of 1933, as amended, or 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 Ownership of Our Common Stock—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, which often has the effect of depressing the market price of a company's stock and could result in a reduced offering 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. For example, we will need to obtain stockholder approval to sell more shares of our common stock to Lincoln Park under our equity line arrangement due to the limitations described above related to sales at less than the Minimum Price.

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 other 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, certain of 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 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” below.

Women’s health has historically been an underfunded sector. In recent years, a number of public companies focused in women’s health 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, sexual health, pelvic pain, fertility, infectious disease and menopause. 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. Non-oncologic women's health therapeutics product launches in recent years have not been perceived as successful. Those perceived commercial failures and 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. While women's health recently has received more attention, and investment in the women's health sector has seen progress with new or increased funding programs from the federal government, it remains an underinvested sector. Further, there is a high level of uncertainty regarding whether the federal government under the current U.S. presidential administration will continue programs initiated by the prior presidential administration that led to increased funding for research and development in women’s health. 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.

Uncertainty in U.S. federal government funding and contracting policies may adversely affect our business.

Changes in federal funding and contracting policies under the current U.S. presidential administration could materially impact the progress of certain of our development programs, including DARE-HPV, as well as our operating results and financial resources. We have received federal government grants and awards in support of several of our development programs. As discussed elsewhere in this report, our DARE-HPV program is being supported in large part with funding provided by federal agencies. There is no guarantee that such contracts and funding will not be frozen, restricted, or terminated as a result of changes in federal funding and contracting policies. In addition, potential future funding and collaboration opportunities through HHS, NIH or other federal agencies may be delayed, reduced or made unavailable. Further, research and development conducted in collaboration with U.S.-based colleges and universities could be delayed or discontinued due to changes in federal funding and contracting policies relating to

such institutions. These changes could adversely affect our development programs, financial condition, operating results and business plans.

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, in March 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 for a few days. While we were eventually afforded full access to our accounts, there is no guarantee that in the event of a future closure of a financial institution, we would have access to our funds 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.

Risks Related to Product Research & Development and Regulatory Approval

To date, XACIATO is the only FDA-approved product to emerge from our portfolio. The FDA's approval of XACIATO does not provide any assurance or predict that we will be successful in developing or achieving regulatory approval to market 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 current 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. See also ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products" and "–Government Regulation Outside the U.S." above. 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 or demonstrate a level of contraceptive effectiveness that will enable it to compete effectively in the contraceptive

market. As another example, while data from our exploratory Phase 2b RESPOND study of Sildenafil Cream allows us to advance Sildenafil Cream into Phase 3 development, the co-primary efficacy endpoints of the Phase 2b study were not met and there is no guarantee that our planned Phase 3 clinical studies, which will have the same co-primary efficacy endpoints used in the Phase 2b study, 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.

Outcomes of our clinical trials, particularly later-stage clinical trials, including our ongoing Phase 3 study of Ovaprene, may significantly impact our stock price and our business prospects. If interim, preliminary or final results from our clinical studies are not positive, or are perceived by third parties, including the medical community, current and potential collaborators, and the investment community, 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. If a product candidate fails to demonstrate adequate safety or effectiveness in a clinical 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.

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.

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 of clinical development milestones, such as 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 its protocol or 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;
- 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 SAEs 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 public health emergency, natural disaster, or worker strike, 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 subject to compliance with extensive regulatory requirements, in some cases is complex, 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. For example, if the ongoing pivotal clinical study of Ovaprene required far more clinical product supplies than were manufactured for prior clinical and nonclinical studies combined. 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, impacting our development timeline. 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. Disruptions and delays in scaling up manufacturing of our product candidates for later stage clinical studies may have 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.

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. See also ITEM 1. “BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products” and “–Government Regulation Outside the U.S.” above. If our contract manufacturers are unable to produce sufficient quantities of our product candidates (or their APIs) for clinical trials or, if approved for commercial sale, 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, delay regulatory approval or disrupt commercial supply and may not achieve the intended objectives. Manufacturing costs may negatively impact the commercial viability of our product candidates, if approved for commercial sale.

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, increase the risk of manufacturing disruptions, and result in higher development costs or costs of goods sold” 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 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 female sexual dysfunction, such as FSAD, are complex. While we worked with experts to select existing as well as 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, there is no precedent program that has utilized these same endpoints in a Phase 3 study and there is no assurance they will be adequate to detect a treatment effect. In addition, 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. While post-hoc analyses of data from the Phase 2b RESPOND study identified a subset of participants that achieved statistically significant improvement in one of the co-primary efficacy endpoints of the study and the planned Phase 3 study will be in that subset of patients, there can be no assurance that Sildenafil Cream will be successful in the planned Phase 3 study.

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 study participants properly, the results of our clinical trials are unlikely to demonstrate effectiveness of Sildenafil Cream. Conversely, screening procedures 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 guarantee that the use of Sildenafil Cream will meaningfully improve their sensations of arousal or demonstrate statistically significant improvement in the primary or secondary efficacy endpoints of the study. 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 will 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 complete 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. See also ITEM 1. “BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products” and “–Government Regulation Outside the U.S.” above.

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.

A change in the regulatory approval pathway we anticipate for a product candidate could significantly increase development cost and timeline and heighten the risk of failure.

We expect to utilize the FDA’s Section 505(b)(2) pathway for most of our current product candidates, including all of our clinical-stage candidates other than Ovaprene, 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.

Section 505(b)(2) of the FDCA permits the filing of an NDA in which the applicant relies, at least in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its NDA, potentially eliminating or reducing the need to conduct certain nonclinical testing or clinical studies and expediting development timelines relative to the traditional or "full" NDA under Section 505(b)(1) of the FDCA. See ITEM 1. “BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Prescription Drugs–Marketing Application Submission and FDA Review” above for more information. If the FDA changes its 505(b)(2) policies and practices, if Congress were to amend the FDCA, or if the current 505(b)(2) pathway is otherwise not available for a product candidate as anticipated, we likely would need to conduct more clinical trials

and nonclinical testing than planned to generate additional safety and efficacy data and other information to support an NDA. 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. In addition, 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, and the filing of a patent infringement lawsuit against us following our submission of a 505(b)(2) NDA could significantly delay any potential FDA approval of the 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 or commercial launch.

In regard to Ovaprene, 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. 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. See ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Combination Products," above for more information about the FDA review and approval process for combination products. 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.

If we are unable to pursue FDA approval via the FDA's 505(b)(2) pathway or, in the case of Ovaprene, through review of a PMA by CDRH, new competitive products may reach 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, and in the case of Ovaprene, review of a PMA by CDRH, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Some of our product candidates 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 approval.

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. See ITEM 1. "BUSINESS–Government Regulation–U.S. Government Regulation–FDA Review and Approval Process for Combination Products," above. 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.

The FDA's shift toward "radical transparency," including plans to release future complete response letters promptly after they are issued to drug product sponsors and increase oversight and enforcement for violations of direct-to-consumer drug advertising, could adversely impact our business and commercial prospects.

There has been recent regulatory activity and enforcement in the United States stemming from an announced shift by FDA toward "radical transparency" resulting in increased scrutiny and transparency in the pharmaceutical drug space that may impact our business.

In July 2025, the FDA announced its intent to increase transparency by publicly releasing CRLs issued to drug and biologic product sponsors and, in September 2025, announced that, going forward, it would publicly release future CRLs promptly after they are issued to product sponsors, describing it as "real-time release" of future CRLs, and, when approving new drug or biologic product applications will release all CRLs associated with that application.

The FDA also released a number of previously unpublished CRLs issued since 2024 associated with pending or withdrawn applications. CRLs, which are issued when an application for marketing approval of a new drug or biologic product cannot be accepted in its current form, outline the reasons for non-approval and may contain confidential or proprietary information relating to the sponsor's product, including clinical trial, chemistry, manufacturing and controls, and technical information, and specific observations about study design and clinical endpoints. Although the FDA has stated that all CRLs will be redacted to remove confidential commercial information, trade secrets, and personal private information, it remains unclear how such redactions will be implemented. Any public release of a CRL issued to us or a collaborator could result in the inadvertent disclosure of information that could compromise our confidential and proprietary information, including our trade secrets and know-how, or facilitate third-party efforts to design around or challenge the validity, enforceability, or scope of our patents, accelerating the development of competitive products. Moreover, once a CRL is published, we may have limited ability to correct or contextualize the FDA's statements. If we were to modify or limit the information shared with the FDA to mitigate such risks, it could increase our costs, slow our regulatory interactions, or delay our product approval timelines.

Further, in September 2025, HHS and the FDA announced a series of measures to address "misleading" direct-to-consumer (DTC) prescription drug advertisements. The measures include (1) initiating rulemaking to close the "adequate provision" requirement, which permits drug manufacturers to include a general statement of risk alongside a webpage or publication and 1-800 number to access the full product labeling, (2) aggressive deployment of its available enforcement tools, including artificial intelligence and other technology-enabled tools to monitor drug ads for DTC violations, and (3) expanded oversight of prescription drug advertising on social media. On September 9, 2025, FDA issued thousands of letters to pharmaceutical companies directing them to remove any noncompliant advertising and bring all promotional communications into compliance. Later in September 2025, the FDA released about 80 warning letters, the majority of which targeted compounding pharmacies and telehealth companies for misleading claims about compounded drugs, including sildenafil, underscoring the FDA's previously stated and growing concern over consumer confusion and medications that lack FDA approval and marking a clear shift in the FDA's enforcement strategy for compounded drugs. Although we have not received an enforcement letter from FDA relating to our specific advertising and promotional activities, there is no assurance that we will not receive one in the future. We continue to actively monitor the evolving regulatory landscape and follow the marketing regulations required by the FDA. Nevertheless, these new policies of radical transparency and increased enforcement could result in unforeseen reputational, operational, financial, regulatory and legal consequences for our company and have the potential to impact our business and how we market our products.

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 could be materially harmed, and we could also be subject to potential claims and lawsuits.

Pre-clinical product candidates may be undervalued 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 and other non-dilutive funding awards supporting several of our development programs do not guarantee that the pre-clinical or clinical development work being funded will be successful or that we will be able or will choose to fund the additional development work that will be required in the future to advance the product candidates toward regulatory approval.

The grants and other non-dilutive funding supporting development of several of our programs should not provide any assurance that pre-clinical or clinical development supported by that funding will be successful, or, even if we are successful with all specified development activities, that we will be able or will choose to fund the additional development work that will be required to continue to advance the product candidates toward commercialization. Further, the grant agreements or other non-dilutive funding award agreements supporting these development programs generally feature milestone-based payments or, in the case of NIH grants, payments are received in reimbursement of specified activities, and there is no assurance that we will be able to achieve or otherwise demonstrate satisfaction of the specified development and reporting milestones required to receive future payments under the agreements. Additionally, the counterparties to these agreements may modify, suspend, discontinue payment of funds or terminate the agreements in certain circumstances largely in their discretion. Accordingly, we may never receive future payments under these agreements or realize the full potential amount of the grant or other funding award.

Risks Related to Our Dependence on Third Parties

Our existing product development and commercialization collaboration is important to our business, and future collaborations may also be important to us. If we are unable to maintain our existing collaboration, if it is 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 an out-license agreement with Organon for the commercialization of XACIATO. We intend to seek additional strategic collaborations, including for Ovaprene, if approved for commercial sale, as a result of the termination of our prior strategic collaboration with Bayer. However, such strategic collaboration opportunities may not be available to us for a variety of reasons. For example, certain potential pharmaceutical company collaborators have announced discontinuation or significant reduction in their research and development efforts in women's health therapeutics. To the extent we do enter into strategic collaborations similar to our agreements for the commercialization of XACIATO, the successful development and commercialization of our products and product candidates may become partially or entirely 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 collaboration, 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, as was the case with our former out-license agreement for Ovaprene, our out-license agreement for XACIATO 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.

Organon has global commercial rights to XACIATO under our exclusive license agreement. 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. As discussed elsewhere in this Risk Factors section, as a result of the traditional royalty purchase agreement we entered into with XOMA, whether we receive any future income based on net sales of XACIATO will depend on whether the Revenue Sharing Threshold is reached, which will depend, in part, on Organon's future commercial success with XACIATO, which is outside of our control. 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.

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 manmade 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 or raw materials suppliers. 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. For example, we do not have any long-term manufacturing or supply agreements with the CMO from which we plan to obtain clinical supplies for our first Phase 3 clinical study of Sildenafil Cream or with the current supplier of the API for Sildenafil Cream. Future supplies of Sildenafil Cream or the raw materials required to produce it may be more difficult and costly to obtain because we do not have long-term supply contracts, which could make us more vulnerable to significant price increases. 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, which is sourced from a supplier located in India, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, future currency fluctuations, increased shipping costs, or new or increased U.S. tariffs and trade disputes with other countries could increase our clinical development costs, and ultimately, our cost of goods sold, which could adversely impact our operating results and financial condition.

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 assumed manufacturing responsibility for XACIATO from us in December 2023, 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 future payments we may receive under the traditional royalty purchase agreement we entered into with XOMA.

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, increase the risk of manufacturing disruptions, and result in higher development costs or costs of goods sold.

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.

We rely on, and intend to continue to rely on, third parties to conduct our clinical and nonclinical studies and execute other significant aspects of our product development programs. Failure of these third parties to successfully carry out their contractual duties, comply with our clinical protocols or 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 third parties. We rely on CROs, medical institutions, clinical investigators, laboratories, vendors and consultants to conduct all of our clinical trials and perform nonclinical testing. These third parties play a significant role in the conduct and timing of our clinical and nonclinical studies and the collection, management and analysis of study data, which are critical to our business. In addition, we have relied, and expect in the future to rely, on third parties to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals for our product candidates. We enter into agreements with these third parties governing their work for us, but we do not control them and have limited influence over their actual performance. They may not devote sufficient time and resources to our projects, or their performance may be substandard, resulting in clinical trial delays, suspensions or terminations, delays in submission of our marketing applications, failure of a regulatory authority to accept our applications for filing or receipt of a CRL. The performance of these third parties may also be negatively impacted by macroeconomic factors, geopolitical conflicts or events, natural or manmade disasters, public health emergencies, information system and cybersecurity incidents, and workforce challenges. In addition, these third parties may have relationships with companies developing competitive products and prioritize a competitor’s clinical or nonclinical studies or regulatory affairs activities over their work for us, which could harm our competitive position. Because of our dependence on these third parties, if they fail to meet expected deadlines, adhere to our study protocols, meet regulatory and legal

requirements, or otherwise perform in a substandard manner, we could suffer significant delays and additional costs in, and potentially failure of, the development of one or more of our product candidates.

Our CROs, study sites and other consultants generally have the right to terminate their agreements with us without cause upon the completion of a specified notice period, subject to limited restrictions. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner, or at all. Switching or adding additional CROs, study sites, and other third party service providers due to substandard or inadequate performance or termination of a relationship involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our communicated clinical development timelines. Though we work to carefully manage our relationships with our CROs, study sites, and other third parties, we have encountered challenges and delays in our clinical and nonclinical studies as a result of performance issues in the past, and there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

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 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.

In May 2018, we completed our acquisition of Pear Tree and obtained exclusive global rights to certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration, which led to our DARE-VVA1 program. Under the applicable license agreements, as amended, we are required to use commercially reasonable efforts or reasonable best efforts to bring licensed products and processes to market, which include achieving specified milestones. The licensors may terminate the agreements for failure to make certain payments due to the licensors and any uncured material breach or default, including breach of our diligence obligations. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development—Pear Tree Acquisition and License Agreements," above.

In August 2023, we entered into a license agreement with Douglas for 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 commenced our DARE-HPV program. Under this agreement, we must use commercially reasonable efforts to develop and introduce to market at least one product or process, which efforts include achieving specific diligence requirements by dates specified in the agreement. Douglas may terminate the agreement for any uncured failure to make certain payments, any uncured material failure to fulfill our diligence obligations, or any other uncured material breach of our other obligations under the agreement. See ITEM 1. "BUSINESS-Strategic Agreements for Pipeline Development—Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement," 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 and our ability to receive milestone and royalty payments from third-party sublicensees, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 timing and amount of milestone or royalty payments due to the licensor;
- 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 Products We Develop

We have no internal sales, marketing or distribution capabilities, and we may need to invest significant resources to establish those capabilities. If we are unable to timely establish those capabilities on our own or through arrangements with third parties, product launch may be delayed, commercialization may be adversely impacted, and we may not be able to generate product sales revenue.

We currently do not have, and have never had, 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, or collaborating with third parties that have established sales forces and distribution systems, either to augment our own sales force and commercial infrastructure or in lieu of establishing our own sales force and commercial infrastructure. We currently have no commercialization agreements with third parties other than our license agreement with Organon for XACIATO. We may not be able to maintain our existing commercial collaboration or establish and maintain other commercial collaborations on favorable terms, on a timely basis, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties to commercialize products we develop than if we were to do it ourselves.

To generate revenue from our product candidates, if approved for commercial sale, we may need to establish our own sales forces and commercial infrastructure. There are significant challenges and risks involved with building and managing a sales organization and other commercial infrastructure, even if we collaborate with third parties that have established sales forces and distribution systems to augment our own capabilities, including:

- difficulties in recruiting and retaining adequate numbers of qualified individuals;
- providing adequate training for sales and marketing and support personnel;
- effectively managing a geographically dispersed sales force;
- difficulties generating sales leads;
- potential lack of complementary products our sales personnel may be able to offer compared with sales personnel for competitive products; and
- unforeseen costs and expenses associated with establishing a new corporate function and the rapid growth of our company.

Recruiting, incentivizing and training a sales force is expensive and requires substantial management time and focus. 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 expenses, and our investment would be lost if we could not retain or reposition our sales and marketing personnel. On the other hand, if we do not timely establish a sales force and other commercial infrastructure, a product launch may be significantly delayed, adversely impacting the potential commercial success of the product, as well as our operating results and financial condition. 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.

Failure or delay in entering into and maintaining arrangements with third parties to market and sell, or assist us in marketing and selling, our product candidates, if approved for commercial sale, or in establishing capabilities to independently commercialize our product candidates could significantly delay commercial launch and negatively

impact their potential commercial success, which could have a material adverse effect on our business, financial condition and results of operations.

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

The pharmaceutical industry is intensely competitive and characterized by rapid technological developments. Moreover, the women's health sector is very fragmented and highly competitive. We anticipate that our product candidates may compete not only with FDA-approved, prescription and over-the-counter, branded and generic drug products, but also compounded drugs, medical devices, dietary supplements, and cosmetics. We face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies and specialty pharmaceutical companies that already possess robust product portfolios and strong franchises in women's health in areas in which we plan to compete, as well as generics manufacturers, compounding pharmacies and other drug compounding facilities, and dietary supplements manufacturers. In addition, academic and other research institutions are and could be engaged in research and development efforts for products in the therapeutic areas targeted by our product candidates. 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.

Many of our product candidates, if approved for commercial sale, 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 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. 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 prescribe a competitive product 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. If our commercial collaborator fails to generate significant net sales of XACIATO which exceed the Revenue Sharing Threshold, we will not have any future revenue stream relating to XACIATO.

The women's health market includes many generic FDA-approved drug products, compounded drugs, as well as dietary supplements and consumer health products, and growth in these categories is expected to continue, which could make the successful introduction of our products difficult and expensive.

The proportion of the U.S. drug market made up of generic products has been increasing. In addition, compounded drugs and dietary supplements in women's health are multi-billion dollar markets. As a result, even if our product candidates are approved, it may be more difficult for us or a commercial collaborator to introduce a new product, particularly a branded prescription product, 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 we seek to compete. Our product candidates for menopause symptoms will

additionally have to compete with compounded hormones supplied by compounding pharmacies and other drug compounding facilities, as well as dietary supplements marketed for relief of menopause symptoms. Compounded sildenafil cream medications are also currently being supplied by compounding pharmacies and other drug compounding facilities. 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 as compared to what other available products have demonstrated.

Additional marketing and educational efforts may be required to introduce a new branded prescription medical product in order to overcome use of generic products, compounded drugs and dietary supplements 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, compounded drug, or dietary supplement rather than pay out-of-pocket or a higher co-pay for our product, our sales revenues or royalties and other license fees, as applicable, will be limited and we may never become profitable.

Our product candidates 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.

The commercial success of any product we develop and bring to market, or is marketed by a licensee, will depend significantly on the broad acceptance of the product by physicians, patients, and others in the medical community, as well as, in many cases, third-party payors. The degree of market acceptance of our products will depend on several factors, including:

- the indication for which the product is approved;
- the timing of market introduction of the product and availability of alternative treatments and products for the same indication;
- the demonstrated clinical efficacy and safety of the product, including as compared to alternative products;
- the terms of regulatory approval, such as any restrictions on the use of the product together with other medications, or required warnings in the product labeling;
- the prevalence and severity of any adverse side effects associated with the product, including as compared to alternative treatments and products;
- the convenience and ease of administration for patients, including as compared to alternative treatments and products;
- the willingness of the target patient population and prescribing physicians to try a new product ;
- the effectiveness of the sales and marketing strategy and efforts for the product, including the success of efforts to educate the medical community and third-party payors regarding the benefits of the product;
- the pricing and cost-effectiveness of the product, including as compared to alternative treatments and products;
- the availability and extent of third-party coverage and reimbursement for the product;
- the willingness of patients to pay all, or a portion of, the out-of-pocket cost for the product in the absence or insufficiency of third-party payor coverage and reimbursement;
- unfavorable publicity relating to the product or products with the same or similar APIs, or favorable publicity about competing therapies or products; and
- the existence and extent of pending or potential product liability claims.

If XACIATO or any future product does not achieve an adequate level of market acceptance, the product may not generate significant revenue or may generate substantially less revenue than anticipated, which could have a material and adverse effect on our business, financial condition, results of operation and prospects. We may suffer reputational harm and we may never become profitable.

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 those discussed elsewhere in these "Risks Related to Commercialization of Products We Develop" and "Risks Related to Our Intellectual Property" below, as well as the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product, preferences by health care providers and women for a vaginally administered therapy, and regulatory approval and market introduction of alternative therapies, including non-antibiotic treatment options. We have limited control over Organon's efforts with respect to XACIATO and there is no assurance they will be successful or that the Revenue Sharing Threshold will be reached. As discussed elsewhere in this Risk Factors section, we will not receive any payments based on product sales until after the Revenue Sharing Threshold is reached. We may suffer reputational harm if XACIATO is not commercially successful and our ability to raise additional capital or enter into other commercial collaborations could be impaired. See also the risks and uncertainties described under "Risks Related to Our Dependence on Third Parties," above.

The commercial success of Ovaprene, if approved for commercial sale, will depend on the degree of market acceptance of a hormone-free, monthly intravaginal product, clinical efficacy and safety of the product, including as compared to alternative contraceptive methods, pricing of the product, and the availability and extent of third-party coverage and reimbursement for the product.

Today, there is 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, IUDs, implantable rods 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. 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 demonstrate typical use efficacy (or the expected rate of pregnancy protection once the product is used widely under everyday circumstances) that approaches the approximately 93% typical use efficacy at 12 months of current FDA-approved non-implanted, non-injected hormonal contraceptive methods (pills, patches and vaginal rings). Clinical testing will also need to demonstrate that the product can be safely worn for multiple weeks.

If Ovaprene receives regulatory approval, its commercial success, or the success of any other future contraceptive product we develop, including our current early clinical-stage and pre-clinical stage candidates, will depend upon the contraceptive market and market acceptance of an alternative method. Factors expected to impact broad market acceptance of a new contraceptive product include those discussed above under "Our product candidates 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," as well as:

- demonstration of 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 compared with higher dose hormonal contraceptives;
- preference for a monthly format product over contraceptive products to be taken daily or used in the moment;
- preference for an intravaginal product over other formats such as pills, patches, injectables and condoms;
- generic contraceptive options, including generic versions of the hormone-containing intravaginal product NuvaRing®; and
- 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.

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

As a result of the termination of our license agreement with Bayer for Ovaprene in December 2025, we will need to enter into an agreement with a third party to commercialize Ovaprene, for which no assurances can be given, and if we do not enter into such agreement, the commercialization of Ovaprene would be delayed. See also the risk factor titled, "Our existing product development and commercialization collaboration is important to our business, and

future collaborations may also be important to us. If we are unable to maintain our existing collaboration, if it is not successful, or if we are unable to establish additional strategic collaborations, our business and prospects may be materially harmed," above.

The commercial success of an FDA-approved Sildenafil Cream product will depend on the availability of alternative treatments and products, the effectiveness of the sales and marketing strategy and efforts for the product, including the success of efforts to educate women and their health care providers about FSAD, and the availability and extent of third-party coverage and reimbursement for the product, among other factors.

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. In addition, an FDA-approved Sildenafil Cream product may also have to compete with compounded drugs. Some compounding entities currently supply topical cream formulations of sildenafil. In addition, some compounding entities have partnered with telemedicine providers, enabling them to expand the potential market for their compounded drugs. The availability of cream formulations of sildenafil through compounding entities, could make it more challenging for Sildenafil Cream to build and maintain market share. Even if we achieve our goal of being first-to-market for FSAD, the costs associated with introducing a new branded prescription product into the female sexual dysfunction market would likely be significant, and regardless of the amount spent, there is no guarantee that our new product will be broadly adopted. Broad market adoption of Sildenafil Cream will depend not only on Sildenafil Cream's ability to demonstrate safety and effectiveness in treating FSAD in Phase 3 clinical trials, but a variety of factors, as discussed above under "Our product candidates 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." If we or a commercial collaborator are not successful in increasing awareness and understanding about FSAD and Sildenafil Cream, the market potential of Sildenafil Cream will not be realized. Women who experience low or no genital arousal may be hesitant to seek treatment due to stigma and embarrassment associated with sexual health issues, lack of understanding of normal versus abnormal sexual functioning, or lack of awareness that FSAD may be treated with medication. Health care providers may be hesitant to prescribe Sildenafil Cream for many reasons, including lack of understanding or experience with female sexual dysfunction in general and FSAD in particular, lack of experience with any product approved to treat FSAD, or perceived lack of clinical evidence of the safety and efficacy of Sildenafil Cream. Women may also be hesitant to use Sildenafil Cream for many reasons, including the lack of experience with any product designed to treat FSAD, concern over potential side effects, and the out-of-pocket cost of Sildenafil Cream, particularly if it is not covered by insurance. Currently, third-party payors such as government health care programs and private insurance companies often do not cover products prescribed to treat female sexual dysfunction disorders. If Sildenafil Cream is not an affordable option for a significant segment of potential users, the ability to build a commercial market for Sildenafil Cream will be significantly impaired.

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. 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, to 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.

The commercial success of DARE-HRT1, if approved for commercial sale, will depend on the availability of alternative products for managing menopause symptoms, concerns about the safety of hormone therapy, and women's preferences, among other factors.

DARE-HRT1, if approved as a treatment for moderate to severe VMS due to menopause, will compete with the many options on the market targeted to or FDA-approved for the treatment of menopausal symptoms, including VMS. Such options include hormone therapies in the form of pills, patches and creams, some of which are FDA-approved products and others which are supplied by compounding entities, as well as non-hormonal options, including an FDA-approved products Veozah® (fezolinetant) marketed by Astellas Pharma and Lynkuet® (elinzanetant) marketed by Bayer, and dietary supplements. Both the supplement and the compounded hormone therapy markets are very significant. A considerable segment of the compounded hormone therapy market is comprised of compounded hormones in pellet form that are implanted under the skin as a non-daily alternative, which could be directly competitive with DARE-HRT. We expect the options for hormone therapy and non-hormonal therapies to continue to expand with time. DARE-HRT1 is designed to offer a convenient vaginal ring that

continuously delivers a combination of bioidentical estradiol and progesterone over 28 days. Bioidentical hormones refer to compounds that are chemically identical to those produced naturally in the human body. Studies have not demonstrated that bioidentical hormones are safer than synthetic 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 include:

- women's preference for vaginal ring delivery of hormone therapy over pills, patches and creams;
- women's preference for a monthly product format over products to be taken or applied daily;
- data regarding symptom relief of DARE-HRT1 compared with other treatments and products for VMS;
- preference for bioidentical hormones by women and health care providers;
- positive or negative news and research regarding hormone therapy in general and bioidentical hormone therapy in particular;
- preference for an FDA-approved product by women and health care providers over treatments prepared in compounding entities;
- the success or failure of other FDA-approved bioidentical hormone products and FDA-approved non-hormonal products for VMS;
- 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.

Potential safety concerns regarding hormone therapy could adversely affect our business.

Women have used hormone therapy products for decades to manage menopausal symptoms. However, the use of hormone therapy has been, and continues to be, the subject of scientific debate and regulatory and public health scrutiny. Published clinical studies have associated certain forms of hormone therapy with potential serious safety risks, including an increased likelihood of cardiovascular events, stroke, blood clots, probable dementia, and certain hormone-sensitive cancers, including breast cancer and endometrial cancer. Although the studies have indicated that the nature and magnitude of these risks may differ materially depending on the type of hormone therapy, the route of its administration, patient age, proximity of initiation of hormone therapy to menopause onset, duration of use, and individual patient characteristics, heightened attention to these issues may influence prescribing behavior, patient acceptance, and regulatory expectations. In November 2025, HHS announced that the FDA was initiating the removal of broad “black box” warnings from hormone replacement therapy products for menopause following a comprehensive review of the scientific literature, an expert panel on the risks and benefits related to menopause hormone therapy in July 2025, and a public comment period. Specifically, the FDA announced it will work with companies to update language in hormone replacement therapy product labeling to remove references to risks of cardiovascular disease, breast cancer, and probable dementia. The FDA is not seeking to remove the boxed warning for endometrial cancer for systemic estrogen-alone products. However, the longstanding controversy over hormone therapy may continue to shape public perception and influence prescribing behavior.

Historical precedent illustrates the potential magnitude of these impacts. In 2002, alarming results from the Women’s Health Initiative (WHI) study, a large, long-term government-funded study, were released suggesting that varying forms of systemic hormone therapy that included estrogen and progesterone could increase risks of cardiovascular problems, breast cancer, endometrial cancer, and probable dementia. Media coverage was widespread and, shortly after, the FDA implemented a broad “black box” warning on all menopause treatments containing estrogen. In the months and years following the 2002 WHI publication, millions of women discontinued hormone therapy and the hormone therapy market contracted substantially. While more recent analyses of the WHI study suggested flaws in the original findings and findings from subsequent studies have led to more nuanced hormone therapy guidelines and recommendations, including those issued by the Menopause Society, there have been lasting effects on prescribing behavior, patient attitudes, and regulatory labeling.

If new data, safety signals, or adverse event reports emerge, whether or not directly related to our hormone therapy products or product candidates, we could face negative publicity, reduced demand, increased regulatory oversight, labeling changes, reclassification of product risks, additional post-marketing requirements, or restrictions or contraindications on use. The FDA or professional medical organizations may also update treatment guidelines or recommendations in ways that discourage or limit hormone therapy use, narrow the indicated patient population,

recommend alternative treatments, or otherwise reduce the commercial opportunity for hormone therapy products, as was seen following the 2002 WHI publication. Any of these developments could adversely affect commercial introduction and sales of DARE to RECLAIM estradiol progesterone intravaginal ring, impede further clinical development and potential regulatory approval of our hormone therapy product candidates, require additional clinical studies, and materially harm our reputation, business, financial condition and results of operations.

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 and adversely affect sales of XACIATO in the U.S. and inhibit or delay its development, approval or commercialization outside of the U.S., which could, in turn, have a significant negative impact on potential payments to us under the traditional royalty purchase agreement we entered into with XOMA, 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 any of our product candidates, or about adverse event reports on XACIATO, 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 our stock price.

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 medically necessary or 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 a product, 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 for commercial sale, 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 for commercial sale.

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 for commercial sale. 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 for commercial sale, 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.

Manufacturing disruptions could cause significant delays and disruption in the commercial launch and/or supply shortages of any product we develop.

The manufacture of drug products and drug/device combination products can be complex and is 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, increase the risk of manufacturing disruptions, and result in higher development costs or costs of goods sold.”

If competitors obtain approval for generic versions of our products, our business may suffer.

XACIATO and any future product we develop 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 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 Section 503B Compounding

We plan to generate revenue from sales of DARE to PLAY and other potential 503B compounded drugs, but we have limited experience in this line of business and may not be successful in our efforts.

One aspect of our 503B business strategy is to enter into arrangements with outsourcing facilities through which we can generate revenue from sales of DARE to PLAY and other potential 503B compounded drugs produced by those outsourcing facilities under Section 503B. Other than entering an arrangement with Bravado, the 503B outsourcing facility for DARE to PLAY, in 2025, we have never entered into arrangements with outsourcing facilities. Although we have entered into the arrangement with Bravado, we may need to identify and enter into additional satisfactory arrangements with one or more other outsourcing facilities in order to successfully execute our commercialization strategy, and no assurances can be given that we will be successful in doing so on commercially reasonable terms or at all. Even if we are successful in this regard, we may not generate sufficient revenue to recover our costs. Establishing such additional arrangements could be expensive and time consuming, disrupt our other operations, require significant capital expenditures and distract management and our other employees from other aspects of our business.

We are and will remain reliant on Section 503B-registered outsourcing facilities to produce DARE to PLAY and potentially other 503B compounded drugs, and their failure to adequately perform their obligations could harm our reputation, business and financial condition.

We have entered into an arrangement with one outsourcing facility for the compounding and distribution of DARE to PLAY, and we may enter into additional arrangements with one or more outsourcing facilities for DARE to PLAY or other potential 503B compounded drugs. We are reliant on our current outsourcing facility, and will be reliant on any future outsourcing facilities, to compound and distribute DARE to PLAY and any other 503B compounded drugs, and to comply with applicable statutory and regulatory requirements, including FDA's cGMP regulations and related FDA guidance for drugs compounded at outsourcing facilities. Outsourcing facilities have been subject to increased scrutiny of their compounding activities by the FDA and state governmental agencies. Governmental inquiries or actions or litigation brought against us or any of our outsourcing facilities, whether or not such inquiry, action or litigation ultimately results in penalties, changes to our business practices or other consequences, could have an adverse effect on our reputation, business and financial condition. We are also reliant on suppliers that supply sildenafil citrate and potentially other active pharmaceutical ingredients to the outsourcing facilities. We do not

control or direct the compounding or distribution process used by these parties, and we have no control over their ability to maintain adequate quality control, quality assurance and qualified personnel. These arrangements also involve other risks, including:

- the inability of third parties to consistently meet product specifications and quality requirements;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- third parties may not be able to appropriately execute necessary manufacturing procedures and other logistical support requirements;
- third parties may fail to comply with cGMP requirements and other FDA or other comparable regulatory requirements;
- breach, termination or non-renewal of agreements in a manner or at a time that is costly or damaging to us;
- inability to procure or maintain state licenses in those states into which DARE to PLAY or any other 503B compounded drugs are shipped;
- third parties may not devote sufficient resources to our needs;
- the operations of third parties could be disrupted by conditions unrelated to our business or operations; and
- logistics carrier disruptions or increased costs that are beyond our control.

In addition to the risks enumerated above, our ability to commence and sustain commercial distribution of potential 503B compounded drugs is subject to the completion of process validation at outsourcing facilities we engage. Under FDA's cGMP regulations applicable to Section 503B outsourcing facilities, commercial distribution of a compounded drug formulation from a Section 503B outsourcing facility generally requires the satisfactory completion of process validation protocols demonstrating that the manufacturing process consistently produces a product meeting its predetermined specifications and quality attributes. As of the date of this report, process validation for DARE to PLAY has not been completed. Until process validation is successfully completed, commercial distribution of DARE to PLAY may be delayed. Process validation may take longer than anticipated, may reveal deficiencies requiring remediation, or may ultimately not be achievable with the current outsourcing facility, any of which could materially delay or prevent the commercial launch of a potential 503B compounded drug.

Adverse developments affecting the supply of sildenafil citrate or other active pharmaceutical ingredients, or the compounding or distribution operations of parties involved in the compounding and distribution of DARE to PLAY or any other 503B compounded drugs, may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the availability of DARE to PLAY or such other 503B compounded drugs. We may also have to undertake costly remediation efforts, or seek more costly supply, compounding and distribution alternatives.

Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, total or partial suspension of production, or issuance of a Form 483 or Warning Letter.

Our commercialization strategy for DARE to PLAY and other potential 503B compounded drugs relies on, and will rely on, third-party telehealth platforms, dispensing pharmacies, and other commercial partners, which subjects us to a variety of regulations and related potential liability.

We have entered into arrangements with third-party telehealth platforms, dispensing pharmacies, and other commercial partners in connection with bringing DARE to PLAY to market, and we may enter into additional arrangements for DARE to PLAY or other 503B compounded drugs we seek to bring to market. The FDA has intensified its enforcement posture with respect to the promotion and advertising of compounded drugs, and particularly compounded products marketed through telehealth channels. In September 2025, the FDA announced measures to address misleading direct-to-consumer prescription drug advertisements and issued enforcement correspondence directed at compounding pharmacies and telehealth companies for misleading claims about compounded drugs, including compounded sildenafil specifically. The FTC also actively monitors advertising and marketing claims for consumer health and pharmaceutical products and may take enforcement action against claims it deems to be unfair or deceptive. Allegations, litigation, or regulatory investigations brought against us or any of our commercial partners relating to the promotion, advertising, fulfillment, distribution, and/or sale of any of the 503B compounded drugs we bring to market, whether or not such litigation or investigation ultimately results in penalties, changes to our business practices or other consequences, could have an adverse effect on our reputation, business and financial condition.

The litigation and regulatory proceedings we could face may be protracted and expensive, and the results are difficult to predict. Such litigation or regulatory proceedings and investigations, unexpected side effects or safety or efficacy concerns with DARE to PLAY or any other 503B compounded drug we bring to market or related negative publicity could have an adverse effect on our reputation, business and financial condition.

In addition, the practice of telemedicine, and the prescribing of compounded prescription drugs through telehealth platforms, is subject to a patchwork of state laws governing the practice of medicine, prescribing, and pharmacy licensure. The ability of our dispensing pharmacy partners to ship compounded drug products to patients may be limited by state pharmacy laws and licensure requirements, and any inability of our commercial partners to procure or maintain required state licenses could restrict or prevent distribution of DARE to PLAY or any other 503B compounded drug in certain states, which could materially limit our addressable market. State legislatures and regulators continue to develop and revise rules governing telehealth prescribing, including with respect to the establishment of valid prescriber-patient relationships, mandatory in-person examination requirements, and permissible modalities for telehealth consultations. Changes in state law or enforcement of existing requirements could restrict or eliminate our commercial partners' ability to prescribe, dispense, and ship DARE to PLAY or any other 503B compounded drug in particular states.

We cannot guarantee that all promotional materials, digital marketing, social media content, or other patient-facing communications generated or used by us or our commercial partners will fully comply with FDA, FTC, and applicable state requirements at all times. Any finding of non-compliance — whether directed at us or at a commercial partner — could result in warning letters, required corrective advertising, civil penalties, injunctive relief, or other enforcement action, and could require material changes to our marketing practices. Even if any such enforcement action is ultimately resolved in our favor, it could negatively affect demand for the 503B compounded drugs we bring to market, harm our reputation, and adversely affect our business.

Achieving and maintaining market acceptance of DARE to PLAY produced and distributed under Section 503B could be negatively impacted by perceived risks associated with compounded drugs.

Compounded drugs are not FDA-approved products; lawfully compounded drugs are specifically exempt from FDA approval pursuant to Section 503B(a). Some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, a compounded drug for a variety of reasons, including because it is not required to be, and has not been, approved for marketing and sale by the FDA. In addition, certain outsourcing facilities have experienced both facility and product quality issues and been the subject of negative media coverage and litigation, and the actions of these facilities have resulted in increased scrutiny of compounding activities. Our ability to generate revenue from sales of DARE to PLAY produced and distributed under Section 503B will be adversely impacted if we are unable to achieve and maintain market acceptance for it.

Sildenafil citrate must remain on the list of bulk substances that may be used in compounding under Section 503B, and if it were to be removed, we would be unable to offer DARE to PLAY under Section 503B.

Sildenafil citrate is currently listed among those nominated substances for which bulk drug substance may be used in compounding by Section 503B-registered outsourcing facilities; the so-called "Category 1" list pending FDA's evaluation. However, we have no control over whether sildenafil citrate will remain on the list of bulk drug substance that may be used in compounding by outsourcing facilities or for how long. If sildenafil citrate is removed from the list, we would be unable to offer DARE to PLAY via a Section 503B-registered outsourcing facility, and it could harm our reputation, business and financial condition.

In addition, a third party could request that the FDA remove sildenafil citrate from the list of bulk substances that may be used in compounding by Section 503B-registered outsourcing facilities. If removed from such list, outsourcing facilities would be prohibited from producing any compounded drug that includes sildenafil citrate, including DARE to PLAY. For information regarding how the FDA intends to evaluate whether there exists a clinical need for compounding with a bulk drug substance, see "Regulation of Compounded Drugs," below.

If a compounded drug formulation provided by an outsourcing facility leads to patient injury or death, or results in a product recall, we may be exposed to significant liability and reputational harm.

The success of DARE to PLAY produced and distributed under Section 503B will depend to a significant extent upon perceptions of product quality. We could be adversely affected if DARE to PLAY is subject to negative publicity. We could also be adversely affected if it or similar products sold by other companies, or any products sold by outsourcing facilities that produce DARE to PLAY, prove to be, or are alleged or asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who takes a compounded drug, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper distribution or other uses of the compounded drug, any of which could result from human or other error. Any of these situations

could lead to a recall of, or safety alert relating to, the compounded drug. Similarly, to the extent any of the ingredients used to produce a compounded drug have quality or other problems that adversely affect the finished compounded drug, its sales could be adversely affected. Because of our dependence upon perceptions of prescribing physicians and their patients, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of DARE to PLAY produced and distributed under Section 503B, any similar product sold by other companies, or related to compounded formulations generally, could have a material adverse impact on our reputation, business, and financial condition.

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 25, 2026, we had 24 employees. Our focus on controlling our 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.

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 and increased levels of lawsuits by public company stockholders 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

If we and our licensors are unable to obtain and maintain sufficient intellectual property protection, competitors could develop, market, commercialize or make available products similar or identical to ours, which could significantly limit the commercial potential of our products and product candidates and materially harm our business, financial condition, results of operations, and prospects.

Our success depends in part on our ability, and the ability of our licensors, to obtain, maintain, enforce, and defend patent rights, proprietary know-how, and trademarks of sufficient scope in the U.S. and other countries with respect to our products, product candidates and proprietary technologies. If we are unable to obtain, maintain, enforce and defend sufficient intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed.

We depend heavily on patent rights and other intellectual property in-licensed to us from third parties to protect most of the products and technologies we develop. For some such rights, our third-party licensors control patent strategy and prosecution and we have little, if any, influence or control over such patent strategy and prosecution, and our licensors may not always act in our best interest.

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.

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.

Most of the products we are developing utilize active pharmaceutical ingredients that are not proprietary to us or our licensors and the patents and patent applications owned by us and our licensors intended to protect our products and product candidates relate to specific formulations, processes, methods of delivery, and/or uses, which may not afford sufficient protection against competitors.

The APIs in XACIATO, Sildenafil Cream, DARE-HRT1, DARE-VVA1, DARE-HPV, and other products we are developing are not proprietary to us or our licensors. There are generic drugs available with the same APIs. The patent protection we and our licensors may obtain and maintain for such product candidates are limited to specific formulations, processes, methods of delivery, and/or uses, which may not afford us sufficient protection against competitors. For example, competitors could offer products with the same API as our products in a different formulation or delivery system or for an indication that is outside the scope of our patented formulation, system or use. The commercial opportunity for our products could be significantly harmed if competitors are able to develop or make available alternative formulations with the same APIs or better delivery approaches compared with the products we develop.

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. Our rights to enforce and defend patents we in-license depend upon the terms of our agreements with our third-party licensors, and in some cases, our licensors have the right to control patent enforcement litigation and defense against patent infringement litigation, and we have indemnification obligations for certain losses arising from third-party claims. We also have indemnification obligations under our out-license agreements for XACIATO and Ovaprene, which could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition. Our rights to indemnification by our licensors and licensees may not be adequate to compensate us for losses or the potential loss of our ability to manufacture and sell products. If we were unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

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. Under our subaward agreement with VentureWell, the federal government has a nonexclusive license to obtain access to and to share research results and data, as well as certain rights, including "march-in" rights, in intellectual property conceived, made, created, developed or reduced to practice in our performance of the research activities and objectives relating to advancement of our DARE-HPV program specified in the subaward agreement, pursuant to and in accordance with the Bayh-Dole Act of 1980. During the term of the subaward agreement and for three years thereafter, we are subject to certain restrictions on foreign access to the intellectual property and other technology developed by or for us in or for the provision of such services, including restrictions on our sale or other transfer of such technology to a foreign firm or institution (which would include a sale of our company and a sale or licensing of such technology, but not sales of products or components) without the prior approval of the federal agency providing funding for the subaward agreement. Under our notice of award from NICHD to support the development of DARE-PTB1, the federal government has a royalty-free license to use the patent rights to any invention developed with federal funds support and requires that anyone exclusively licensed to sell any such invention in the U.S. to manufacture it substantially within the country, and the federal government reserves the right to require us to license any such invention to others in certain circumstances.

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 announced that it viewed 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 our grant agreements with the Foundation, we agreed to make 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 the Funded Developments.

Risks Related to Our Business Operations and Industry

Disruptions at government agencies, including due to government shutdowns, other funding shortages, policy changes, leadership changes, layoffs or significant personnel turnover, or public health concerns, could impede development and potential marketing approval of our product candidates and our ability to raise additional capital.

Over the last several years, the U.S. government has shut down several times and certain federal regulatory agencies, such as the FDA and SEC, furloughed or laid off employees and halted non-essential operations due to the failure of Congress to pass a new appropriations bill or continuing resolution to temporarily extend funding. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. A federal government shutdown or other disruption to ordinary course operations could prevent or delay staff at federal agencies from performing key functions that may adversely affect our business, and the more prolonged the disruption, the greater risks it may pose to our business. In addition, considerable uncertainty exists regarding the current U.S. presidential administration's initiatives and how these might impact federal government agencies, including the FDA, NIH, and ARPA-H, their implementation of laws, regulations, policies, and guidance, and their personnel. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our business or operations.

The ability of the FDA to review and approve new product applications or take action with respect to other regulatory matters can be affected by a variety of factors, including funding levels, ability to accept the payment of user fees, ability to hire and retain key personnel, and statutory, regulatory, and policy changes. Government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. For example, the current U.S. presidential administration has issued certain policies and executive orders directed towards reducing, and subsequent reductions have occurred to, the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. Disruptions at the FDA may delay meetings and other communications with or on-site inspections by 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 or prevent providing or processing new grant awards to fund research and development activities and disrupt staff's work and other activities or funding under active grant/cooperative agreements. Moreover, reduced funding levels or leadership and policy changes at HHS agencies could negatively impact our ability to obtain additional grant awards or other non-dilutive federal funding opportunities.

Disruptions at the SEC could prevent or delay 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. If a federal government shutdown halts non-essential SEC operations for an extended period during which we do not have an effective shelf registration statement, it may negatively impact our ability to raise additional capital through registered offerings of our securities.

If a prolonged U.S. government shutdown or other event or condition occurs that prevents or significantly delays the FDA, NIH, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, or if an agency is restructured or experiences significant reduction in funding, leadership changes, workforce reduction or employee turnover, 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.

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 manmade 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 or delays in IRB review and approval of clinical study protocols;
- 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 operational closures or disruptions at our CROs or study sites or 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, government mandates or other changes in terms of employment;
- 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;
- imposition of new or increased tariffs, sanctions, import/export controls or other trade policies that significantly increase the costs of the components and raw materials used in the production of XACIATO or our product candidates;
- 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.

The strategies we implement designed to mitigate the effects or potential effects on our business of a public health emergency, 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 for commercial sale.

Public health emergencies, natural or manmade 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 and for our potential 503B products. 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 for commercial sale. 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 laws and 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. 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 reputational harm.

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, including our CMOs and CROs for our clinical studies, which store sensitive or confidential data of ours, and could compromise the confidentiality, availability and integrity of such information which may be 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, including our CMOs and CROs for our clinical studies, 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. We rely on these third parties to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. However, our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate security measures in place. In addition, we do not have our own information technology department or personnel and rely on third-party information technology consultants to assist our management in assessing, identifying and managing our cybersecurity risks. We do not control these third parties 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, or that of our employees, collaborators, service providers and participants in our clinical studies. 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 general conditions in the global economy and financial markets and geopolitical tensions and 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; new or increased tariffs and other barriers to trade; climate change concerns; or public health emergencies. 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 commercially available. 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 those regarding pay versus performance, compensation clawback, and cybersecurity 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, policies governing 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, 2025, 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, including limitations due to ownership changes that occurred previously or that could occur in the future, and similar limitations may apply under state tax laws. In addition, under legislation enacted by California in 2024, generally, there is a suspension of the NOL deduction for tax years 2024 through 2026 for taxpayers with net business income or modified adjusted gross income of $1 million or more, and a limit of $5 million of business credits on the aggregate use of otherwise allowable business tax credits that any taxpayer could claim for tax years beginning 2024 through 2026. For these reasons, we may not be able to realize a tax benefit from the use of our NOL carryforwards and other tax attributes, even if we attain profitability. 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 8 “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.

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 a new program 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;
- 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 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 or capital commitments by us or our competitors or companies perceived to be economically linked to us;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- 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;
- 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.

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

Our common stock is listed on the Nasdaq Capital Market. To maintain our listing we are required to satisfy continued listing requirements, including the requirements commonly referred to as the minimum bid price rule and with either the stockholders' equity rule or the market value of listed securities rule. The minimum bid price rule requires that the closing bid price of our common stock be at least $1.00 per share, and the stockholders' equity rule requires that our stockholders' equity be at least $2.5 million, or, alternatively, that the market value of our listed securities be at least $35 million or that we have net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years.

We were not in compliance with the stockholders' equity rule or the market value of listed securities rule from August 2024 until July 24, 2025, and we were not in compliance with the minimum bid price rule from July 2023 until July 2024 and from December 2022 until January 2023. Although we regained compliance with the applicable rule in each instance, there can be no assurance that we will continue to satisfy those or other continued listing requirements and maintain the listing of our common stock on the Nasdaq Capital Market.

When Nasdaq confirmed on July 24, 2025, that we regained compliance with the stockholders' equity rule, it also informed us that, pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we would be subject to a mandatory panel monitor for a period of one year from that date, and that if, within that one-year period, the Nasdaq Listing Qualifications Staff, or the Staff, determines that we are out of compliance with the stockholders' equity rule, the Staff will issue a delist determination letter, and we will have an opportunity to request a new hearing with Nasdaq's Hearings Panel. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide a plan of compliance to the Staff with respect to such non-compliance, the Staff will not be permitted to grant us additional time to regain compliance, and we will not be afforded a cure period pursuant to Nasdaq Listing Rule 5810(c)(3). The foregoing would limit our ability to remedy any future non-compliance with the stockholders' equity rule, and would increase the likelihood that our common stock could be delisted, if we were to fall out of compliance with the stockholders' equity rule during the one-year monitoring period.

We were in compliance with the stockholders' equity rule as of December 31, 2025. Based on information currently available to us, our stockholders' equity is expected to be substantially less than $2.5 million as of March 31, 2026. We are actively pursuing initiatives to increase our stockholders' equity, including through our ongoing Regulation A offering and other potential capital-raising activities. If we are unable to demonstrate to Nasdaq that we have increased our stockholders' equity to at least $2.5 million prior to the filing of our quarterly report on Form 10-Q for the quarter ended March 31, 2026, we expect the Staff will issue a delist determination letter. In that event, we intend to request a new hearing with Nasdaq's Hearing Panel, though there can be no assurance that any such hearing would result in a favorable outcome.

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

The sale of our common stock in ATM offerings or under our equity line arrangement 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 and sales of shares of our common stock under our equity line arrangement to fund a significant portion of our operations in prior years, and we may continue to do so to raise additional capital in the future. For example, in 2025, we sold an aggregate of approximately 4.3 million shares of our common stock in ATM offerings and under our equity line arrangement. If we seek and obtain stockholder approval for the sale of additional shares of our common stock under our equity line arrangement, we may sell up to approximately an additional $11.7 million in shares of our common stock under our equity line arrangement. The purchase price for the shares we may sell under our equity line arrangement will vary based on the market price of our common stock at the time we initiate a sale. While sales of shares of our common stock in ATM offerings and under our equity line arrangement 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, 2025, we had outstanding warrants to purchase up to approximately 1.3 million shares of our common stock at a weighted average exercise price of $7.49 per share, outstanding options to purchase up to approximately 1.4 million shares of our common stock at a weighted average exercise price of $9.41 per share, and approximately 0.5 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 9% of the outstanding shares of our common stock as of March 25, 2026, and the underlying shares generally may be freely sold into the public market following exercise of the warrants by the warrant holders. In addition, the issuance of all of the approximately 1.4 million shares of our common stock underlying outstanding options and the approximately 0.5 million shares of our common stock that remained available for future issuance under our stock incentive plan as of December 31, 2025 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, 2025, 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.

In addition, our Restated Certificate of Incorporation, as amended, authorizes us to issue up to 240.0 million shares of our common stock. Subject to limitations imposed by Nasdaq or such other securities exchange on which our securities may be listed, authorized shares of our common stock that are not issued and outstanding or reserved for issuance may be issued without stockholder approval at any time, in the sole discretion of our board of directors, and as of December 31, 2025, only approximately 14.5 million shares were issued and outstanding or reserved for issuance. 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 have designated preferred stock with terms that could reduce the value of our common stock.

Our Restated Certificate of Incorporation, as amended, authorizes us to issue, without stockholder approval, up to 5,000,000 shares of preferred stock, in one or more series, 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. In anticipation of the initial closing of our Regulation A Offering, in January 2026, we filed a Certificate of Designation of Series A Convertible Preferred Stock with the Secretary of State of the State of Delaware that designates 4,999,620 shares of our authorized preferred stock as Series A Convertible Preferred Stock. Our Series A Convertible Preferred Stock ranks, as to rights upon our liquidation, dissolution, or winding up, senior to our common stock. The liquidation preference for each share of our Series A Convertible Preferred Stock is $5.00 per share, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events affecting our Series A Convertible Preferred Stock. As of the filing date of this report, we have issued 65,640 shares of our Series A Convertible Preferred Stock. For additional information regarding the powers, preferences and rights, and qualifications, limitations and restrictions of our Series A Convertible Preferred Stock, see Note 17, “Subsequent Events," to our consolidated financial statements included in this report.

Assuming no change in the authorized number of shares of Series A Convertible Preferred Stock, our board of directors has the authority, without further action by our stockholders, to issue up to 380 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the holders of our common stock. In addition, to the extent that any shares of Series A Preferred Convertible Stock previously designated under the Certificate of Designation referenced in the paragraph above are not issued, our board of directors may, subject to applicable law, redesignate such shares as a new or different series of preferred stock and establish the rights, preferences, privileges and restrictions of such series, any or all of which may be greater than the rights of the holders 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. The chair of our audit committee has a 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 11 "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.

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 25, 2026, we had approximately 32 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

On October 21, 2024, we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. During 2025, we sold 1,470,000 shares of our common stock to Lincoln Park under that purchase agreement for aggregate gross proceeds of approximately $3.3 million. For additional information regarding such sales an our purchase agreement with Lincoln Park, see Note 9 “Stockholders’ Equity—Equity Line” to the accompanying consolidated financial statements. Lincoln Park represented to us, among other things, that it is an “accredited investor” as such term is defined in Rule 501(a)(3) of Regulation D under the Securities Act. The shares of common stock issued to Lincoln Park under the purchase agreement were issued in reliance upon an exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act.

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 purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions. Every innovation we advance is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, pelvic pain to fertility, vaginal health to infectious disease, we’re working to close critical gaps in care using science that serves her needs.

In March 2025, we announced an expansion of our business model to include a dual-path approach to bringing new products to market. For select proprietary formulations, we are pursuing both traditional FDA approval

and earlier market access via Section 503B compounding. We believe this strategy allows us to respond to clinician and patient demand for timely access while continuing to generate the data necessary to seek FDA approval and support long-term value creation. In addition to prescription-based offerings — both FDA-approved products and compounded drugs— we intend to bring to market select consumer health products that do not require a physician's prescription, where appropriate based on product profile and market opportunity.

Section 503B Compounding

Our proprietary topical cream formulation of sildenafil is our first product to market under Section 503B. The compounded drug is branded as DARE to PLAY Sildenafil Cream and became available for pre-order fulfillment by prescription in the U.S. in December 2025. Prescription fulfillment and payment will occur once the product is available for pharmacy dispensing. We expect pharmacy dispensing to commence, and to begin recording revenue from sales of DARE to PLAY in the second quarter of 2026. Because we are in the early stages of executing against our Section 503B compounding strategy and, as an organization, we have no experience in or infrastructure for commercializing products, the amount of potential revenue we may generate during 2026 remains uncertain. We invested approximately $1.0 million to launch DARE to PLAY in 2025, which has been utilized to support a 503B-registered outsourcing facility with technology-transfer activities specific to DARE to PLAY, activate an awareness campaign, and facilitate access to DARE to PLAY as an option for providers and women.

We are also taking action to bring our estradiol progesterone intravaginal ring to market under Section 503B. The compounded product will be branded as DARE to RECLAIM. We are targeting to have DARE to RECLAIM available in early 2027. There are no FDA-approved products that provide estradiol and progesterone together in a non-oral monthly form.

See Item 1. "BUSINESS," in Part I of this report for additional information regarding our Section 503B compounding strategy.

Consumer Health Products - DARE to RESTORE

The first product in our DARE to RESTORE vaginal probiotic suppositories product line, Flora Sync LF5, is expected to become commercially available in the U.S in the second quarter of 2026.

See Item 1. "BUSINESS," in Part I of this report for additional information regarding our consumer health products strategy.

Our Pipeline: Clinical Stage and Pre-Clinical Stage Programs

Our product candidates are in various stages of development, from pre-clinical through a pivotal Phase 3 clinical study, and will require review and approval from the FDA, or a comparable foreign regulatory authority, prior to being marketed and sold. The most clinically advanced product candidates we are developing are: Ovaprene®, an investigational, hormone-free, monthly intravaginal contraceptive currently being evaluated in a pivotal Phase 3 clinical study. Sildenafil Cream, 3.6%, or Sildenafil Cream, an investigational cream formulation of sildenafil, the active ingredient in Viagra®, for topical administration for the treatment of female sexual arousal disorder, or FSAD; DARE-HRT1, an intravaginal ring designed to deliver combination menopausal hormone therapy, bio-identical 17β-estradiol and progesterone together, continuously over a 28-day period for the treatment of moderate to severe vasomotor symptoms, also known as hot flashes; DARE-VVA1, an investigational formulation of tamoxifen in a soft gelatin capsule for intravaginal administration as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse; and DARE-HPV, an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of genital human papillomavirus (HPV) infection in women as well as treatment of cervical intraepithelial neoplasia (also known as cervical dysplasia), and other HPV-related pathologies.

See ITEM 1. "BUSINESS," in Part I of this report for additional information regarding our product candidates.

XACIATO®

The first FDA-approved product to emerge from our portfolio is XACIATO® (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe). XACIATO was approved by the FDA in December 2021, three years after we acquired rights to the program, as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In 2022, we licensed exclusive worldwide rights to develop,

manufacture and commercialize XACIATO to Organon. In January 2024, Organon announced that XACIATO was available nationwide in the U.S. In April 2024, we sold our rights to all royalty and potential milestone payments based on net sales of XACIATO under our agreement with Organon to XOMA. See Note 3 “Strategic Agreements” and Note 13 “Royalty Purchase Agreements” to the consolidated financial statements included in this report for information regarding our exclusive license agreement with Organon and our royalty purchase agreements with XOMA, respectively.

Operations

Our primary operations consist of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or regulatory approval, and commercialization activities for the 503B and consumer health products we seek to bring to market. Until we secure additional capital to fund our operating needs, we will focus our research and development resources primarily on advancement of Ovaprene. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 and DARE-HPV programs, but we also expect such expenses will be supported by non-dilutive funding, with respect to DARE-LARC1, through December 2027, and with respect to DARE-HPV, through October 2026. See Note 15, "Grant Awards" to the accompanying consolidated financial statements for additional information.

We do not have sales, marketing or distribution infrastructure, and currently, we do not intend to build our own sales force or marketing and distribution infrastructure. However, reflecting the shift in our business model, we have been and will be allocating resources to support commercial execution activities, including entering into and maintaining relationships with 503B-registered outsourcing facilities, dispensing pharmacies, telehealth providers and other third parties to help bring our proprietary formulations to market.

As discussed below, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. Our business is subject to a number of risks common to biopharmaceutical companies (see ITEM 1A. RISK FACTORS in Part I of this report) and 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. The commercialization of a product and compliance with 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

Receipt of Payment Under October 2024 Grant Award

In February 2026, we received a $2.0 million payment from CMF under the agreement we entered into with CMF in October 2024 to support the development of DARE-HPV. For a discussion of this agreement, see Note 15, "Grant Awards" to the accompanying consolidated financial statements for additional information. Taking into account this payment, we have received a cumulative total of approximately $7.5 million of the up to $10.0 million in potential funding under the grant award.

Regulation A Offering

On January 27, 2026, we completed the initial closing of our Regulation A offering of up to 4,854,000 units, each consisting of one share of our Series A convertible preferred stock, which is convertible into two shares of our common stock, and two warrants, each exercisable for one share of our common stock at an exercise price of $4.00 per share. The offering price of each unit is $5.00.

The offering is being conducted on a “best efforts” basis pursuant to a selling agency agreement, dated January 5, 2026, between us and Digital Offering, LLC, acting as the lead selling agent for the offering. Digital Offering is not required to sell any specific number or dollar amount of units in the offering.

As of the date of this report, we have issued an aggregate of 65,640 units to investors in the offering, consisting of 65,640 shares of Series A convertible preferred stock and warrants to purchase up to 131,280 shares of our common stock, for gross proceeds of approximately $328,200.

For additional information regarding the Regulation A offering and our agreement with Digital Offering, see Note 17, “Subsequent Events” to the accompanying consolidated financial statements.

Termination of Bayer License Agreement

In January 2020, we entered into a license agreement with Bayer, under which Bayer was supporting the Ovaprene program by providing the equivalent of two experts to advise us in clinical, regulatory, preclinical, commercial, chemistry, manufacturing and controls, and product supply matters, and Bayer had the right to obtain an exclusive license with regard to the commercialization of Ovaprene in the U.S. for human contraception by paying us an additional $20 million fee. We received a notice of termination of the license agreement from Bayer in November 2025, and we agreed with Bayer to terminate the license agreement effective December 2, 2025. Bayer’s election to terminate the license agreement was due to its strategic prioritization. We do not expect the termination of the license agreement to have a material impact on the ongoing pivotal Phase 3 study of Ovaprene. If Ovaprene were to receive marketing approval from the FDA, we will need to enter into an agreement with a third party to commercialize Ovaprene, which could delay the commercialization of Ovaprene. As noted above, we do not have sales, marketing or distribution infrastructure, and we currently do not intend to build such an infrastructure.

Receipt of Grant Funding Installment to Support the Ovaprene Phase 3 Study and Identification & Development of a New Non-Hormonal Contraceptive Candidate

In November 2025, we received a payment of $3.6 million as the latest installment under a grant of up to approximately $10.7 million to support (i) expansion of the number of study sites in the ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in low- and middle-income country settings who need or would prefer to use such a product to avoid an unplanned pregnancy. Additional payments are contingent upon our achievement of specified development and reporting milestones during the term of the grant agreement, which extends through March 2027. See Note 15, "Grant Awards--Other Non-Dilutive Grant Funding--2024 Contraceptive Product Candidate Grant Agreement" to the accompanying consolidated financial statements for additional information regarding the grant agreement.

Nasdaq Listing

On July 24, 2025, we received a letter from the Nasdaq Office of General Counsel confirming that we had demonstrated compliance with the stockholders’ equity requirement in Nasdaq Listing Rule 5550(b)(1) that our stockholders' equity be at least $2.5 million, or the Stockholders’ Equity Rule, and that we are therefore in compliance with the Nasdaq Capital Market's continued listing requirements. We are subject to a mandatory monitoring period of one-year from July 24, 2025. If, within that one-year period, the Nasdaq Listing Qualifications Staff determines that we fall out of compliance with the Stockholders' Equity Rule, the Staff will issue a delist determination letter, and we will have an opportunity to request a new hearing with Nasdaq's Hearing Panel. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide a plan of compliance to the Staff with respect to such non-compliance, the Staff will not be permitted to grant us additional time to regain compliance, and we will not be afforded a cure period pursuant to Nasdaq Listing Rule 5810(c)(3). We were in compliance with the Stockholders’ Equity Rule as of December 31, 2025. Based on information currently available to us, our stockholders' equity is expected to be substantially less than $2.5 million as of March 31, 2026. We are actively pursuing initiatives to increase our stockholders' equity, including through our ongoing Regulation A offering and other potential capital-raising activities. If we are unable to demonstrate to Nasdaq that we have increased our stockholders’ equity to at least $2.5 million prior to the filing of our quarterly report on Form 10-Q for the quarter ended March 31, 2026, we expect the Staff will issue a delist determination letter. In that event, we intend to request a new hearing with Nasdaq's Hearing Panel, though there can be no assurance that any such hearing would result in a favorable outcome. See the risk factor titled, *There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market*, in Item 1A of Part II of this report.

Macroeconomic, Political, and Regulatory Environment Considerations

Our business, financial condition, operating results, and our ability to raise additional capital may be adversely affected by the uncertainty in the U.S. and global macroeconomic, political, and regulatory environments, such as inflation, trade disruptions and restrictive measures, including tariffs, high interest rates, slowed economic growth or recession, uncertainty with respect to the federal budget and debt ceiling, potential or prolonged U.S. government shutdowns, volatility in financial markets, changes in the regulatory landscape in the U.S., including due to significant reductions in funding and staffing of federal agencies and changes in leadership, and geopolitical factors. Unstable and unfavorable market and economic conditions may make it more difficult, more costly, and more dilutive to our stockholders to raise additional capital to fund our operations and execute against our business strategy, as well as

adversely impact market demand for the women's health solutions we bring to market. Further, the service providers, manufacturers, vendors, and collaborators on which we rely may be adversely affected by the foregoing risks, which could directly impact our ability to achieve our operating goals within planned timelines and budgets.

There may be significant future effects on the women's health sector and the pharmaceutical and biopharmaceutical industries as a result of federal policy and regulatory changes under the current U.S. presidential administration, including in areas relating to regulatory framework and oversight, research and development funding, drug pricing reform, global trade policy and tariffs, and others. Recent initiatives have resulted in material reductions in staffing levels at the FDA and NIH, including through workforce reductions and reorganizations, and have impacted the agencies' ability to retain remaining key personnel and hire additional personnel, disrupting their ability to perform routine activities or function in the normal course. A prolonged federal government shutdown with additional agency staff furloughed or laid off could exacerbate these risks. With respect to the FDA, this may result in delays or limitations on our ability to obtain guidance from agency staff, slow review times for applications we submit to commence clinical studies and obtain requisite regulatory approvals in the future, and consequently, negatively impact the cost and timelines for developing and obtaining regulatory approval of our product candidates. Moreover, our business strategy has included seeking non-dilutive sources of funding and collaborations to support product development, and we have benefited significantly from federal government funding through grants and other agreements in support of several of our development programs, including Ovaprene and DARE-HPV. See Note 15 "Grant Awards" to the accompanying consolidated financial statements. Beginning in early 2025, the U.S. presidential administration took actions to freeze or terminate billions of dollars in NIH grants, and the future of the NIH's budget and research funding remains highly uncertain. These actions have already begun to adversely affect the broader research and development funding environment, and our business, financial condition and operating results may be significantly adversely affected if existing grants or other arrangements supporting our development programs are frozen or terminated or we are unable to secure additional grants or other federal government funding in the future. Given the high level of uncertainty regarding federal policy and enforcement and regulatory changes and that circumstances are rapidly evolving, including as a result of legal challenges to recent federal government actions, we are not able to reasonably predict the full extent of the potential impact on our business at this time. We continue to monitor these evolving developments and conditions and their potential impacts on our business, financial condition, and results of operations, and will attempt to adjust our plans, as appropriate, to mitigate risks. For additional information, see the risk factors described in Item 1A. Risk Factors of this report.

Financial Overview

Revenue

Our revenue for 2025 primarily relates to the license fee recognized upon termination of our license agreement with Bayer. Other revenue for 2025 and 2024 were royalties from net sales of XACIATO, which, since April 1, 2024, have been paid to UiE under our royalty interest financing agreement with UiE, and recognized as non-cash royalty revenue.

In the future, we may generate revenue from license fees, milestone payments, and research and development payments in connection with strategic collaborations, and from product sales, including sales of 503B compounded products, consumer health products, and FDA-approved products, if any. We expect to begin recording revenue from sales of DARE to PLAY and Flora Sync LF5 in the second quarter of 2026. Our ability to generate such revenue will depend on the extent to which we are successful in executing against our Section 503B and consumer health product business models, the extent to which the clinical development of our product candidates is successful, and whether we or a strategic collaborator receive the regulatory approvals necessary to market such product candidates, as well as the eventual commercial success of any FDA-approved products. If we fail to successfully achieve any of the foregoing, our ability to generate future revenue and our results of operations would be materially adversely affected.

Cost of Revenues

Cost of revenues primarily represent expenses associated with medical education and consumer awareness related to the commercialization of DARE to PLAY through our 503B business model.

Research and Development Expenses

Research and development, or R&D, represents a core operational focus. We are advancing multiple product candidates through preclinical and clinical development, supported in part by significant non-dilutive grant funding from governmental and non-governmental organizations.

Although our R&D activities remain substantial, as explained in more detail below, grant funding and other financial awards offset a significant portion of our R&D expenses. As a result, our reported operating expenses may appear to be weighted more heavily toward selling, general and administrative, or SG&A, expenses. However, this reflects the reduction to R&D expenses (contra R&D expense) as a result of grant funding and other financial awards, rather than a reduction in our commitment to or investment in R&D activities.

We expect our R&D expenses will continue to represent the majority of our operating expenses, on a pre-contra R&D expenses basis, for at least the next twelve months. R&D expenses consist primarily of:

- direct program costs, including:
  - expenses incurred under agreements with clinical research organizations (CROs), investigative sites and other third parties that assist in the conduct of our clinical trials and nonclinical studies and conduct other R&D and regulatory affairs activities on our behalf,
  - contract manufacturing expenses, primarily for the production of materials for use in our clinical trials and nonclinical studies;
  - expenses related to production of select proprietary formulations by 503B-registered outsourcing facilities prior to commercial launch of the product via Section 503B compounding;
  - transaction costs related to acquisitions of companies, technologies and related intellectual property, and other assets, and
  - milestone payments due to third parties under acquisition and in-licensing arrangements based on our product candidates' achievement of R&D and regulatory milestones specified therein, and
- indirect costs, including:
  - personnel-related costs, including salaries, bonuses, benefits, payroll taxes, and stock-based compensation expenses for employees engaged in R&D functions,
  - the costs of services performed by third parties, including consulting services,
  - facilities-related costs, including rent and maintenance costs, and insurance, depreciation, supplies, and miscellaneous expenses, and
  - costs related to travel, conference participation, service contracts, information technology, dues and subscriptions.

We recognize R&D expenses as they are incurred. External expenses are recognized based on our evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the amount of services that has been performed at each reporting date. Nonrefundable payments we make prior to the receipt of goods or services to be used in R&D are recognized as an expense as the related goods are delivered or services are performed. Milestone payments to third parties under acquisition, license, and option agreements are recognized as they are incurred or when we deem their incurrence to be probable.

We generally track direct R&D costs on a specific basis and present direct costs for our key development programs on a program-by-program basis. We present direct costs for all other programs on a consolidated basis generally by stage of development. Specifically, we present consolidated direct costs for (a) such programs that are in (i) advanced clinical development (Phase 2-ready to Phase 3), (ii) Phase 1 clinical development or that we believe are Phase 1-ready, and (iii) preclinical stage, and (b) other development programs. We do not track indirect costs on a program-by-program basis because those costs generally are deployed across multiple development programs.

We recognize the Australian Research and Development Tax Incentive Program, or the Tax Incentive, as a reduction of R&D expenses (contra R&D expense). The amounts are determined based on our eligible R&D 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 have received, and may in the future receive, funding through grants and other financial awards from governmental entities, private foundations and other organizations that support activities related to the development of certain of our product candidates. As we incur eligible expenses under those grants or awards, we recognize grant funding in our statements of operations as a reduction to R&D expenses (contra-R&D expense). For more information, see Note 2, "Basis of Presentation and Summary of Significant Accounting Policies – Grant Funding" to

the accompanying consolidated financial statements. For the years ended December 31, 2025 and 2024, we recognized contra-R&D expense of approximately $16.4 million and $8.8 million, respectively.

At any one time, we are working on multiple programs at various stages of development. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each development program on an ongoing basis based on our cash position and capital resources and in response to the results of ongoing and future clinical trials and preclinical studies, regulatory developments, and our ongoing assessments as to the commercial potential of each product candidate.

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 R&D 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 R&D expenses due to, among other factors, milestone payments. Conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may not obtain regulatory approval for any product candidate on a timely or cost-effective basis, or at all. Our future R&D expenses and the probability of success of our product candidates may be affected by numerous factors, including the number, scope, rate of progress, expense, and results of our clinical trials and nonclinical R&D activities, the countries in which our clinical trials are conducted, the phase of clinical development of our product candidates, the cost and timing of manufacturing our product candidates, our ability to scale up manufacturing as needed to support later-stage clinical trials and, if approved, commercialization of our product candidates, the extent of changes in government regulation and regulatory guidance relating to development and approval of our product candidates, the timing, receipt, and terms of any clearances to conduct clinical trials and any marketing approvals from applicable regulatory authorities, competition and commercial viability of our product candidates, the extent to which we establish and maintain intellectual property rights, the extent to which we establish and maintain license, collaboration, or other arrangements. As a result, we cannot accurately determine the duration and completion costs of development projects or if, when and to what extent we will generate revenue from any products we develop.

Selling, General and Administrative Expenses

SG&A expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services, commercial-readiness expenses, including for Section 503B compounded drug products and consumer health products, 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. Milestone expenses consist of amounts that become due to third parties under our in-license or other agreements under which we acquired rights to technology or other intellectual property we use in a product based on the product's achievement of commercial milestones specified therein.

Recently Issued Accounting Standards

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations and cash flows is discussed in Note 2 to the accompanying consolidated financial statements.

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;
- Stock-Based Compensation;
- Liability Related to the Sale of Future Royalties
- Sale of Future Payments;
- Grant Funding; and
- Clinical Trial Expense Accruals.

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 $12.8 million in license fee revenue, all of which, other than $1.0 million recognized upon the termination of the license agreement with Bayer, is 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 $26,000 of royalty revenue.

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 10 to our consolidated financial statements included in this report for more information.

Liability Related to the Sale of Future Royalties

In December 2023, we entered into a royalty interest financing agreement with UiE, pursuant to which we sold to UiE an interest in royalty and milestone payments we receive based on net sales of XACIATO. We received $5.0 million from UiE in connection with entering into the royalty interest financing agreement. We account for the sale of future royalties related to the UiE arrangement as debt under ASC 470, Debt. We recognized the $5.0 million payment received as a liability on our consolidated balance sheet because we agreed to make payments to UiE until such time that UiE 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 accounting for this arrangement requires significant judgment in estimating the total amount and timing of future royalty payments expected to be paid over the life of the agreement. These estimates are based on a combination of internal forecasts and external market data, including assumptions regarding future product sales, market adoption, pricing, and other relevant factors that may impact royalty-generating revenues.

The estimated royalty stream is used to determine the effective interest rate applied to the liability, which drives the recognition of interest expense over the term of the arrangement. Because the effective interest rate is based on projected royalty payments, changes in the estimated amount or timing of future royalties could materially affect the amount and timing of interest expense recognized in future periods. We periodically reassess our estimates of expected royalty payments. If actual results differ from our estimates, or if our expectations regarding future royalty payments change, we prospectively adjust the effective interest rate and the recognition of interest expense over the remaining term of the arrangement. Refer to Note 12 to our consolidated financial statements included in this report for more information.

Sale of Future Payments

On April 29, 2024, we entered into and closed a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA pursuant to which we sold our right, title and interest in the following to XOMA (i) all future net royalty and potential net milestone payments we would otherwise receive from Organon based on net sales of XACIATO, (ii) a portion of future net sales of Ovaprene and a portion of the $20.0 million payment that we could have potentially received under our since terminated license agreement with Bayer relating to Ovaprene, and (iii) a portion of future net sales of Sildenafil Cream. We received $22.0 million from XOMA in connection with entering into the royalty purchase agreements. Under the terms of the royalty purchase agreements, if XOMA receives total payments under the royalty purchase agreements equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to us for each successive $22.0 million XOMA receives under the royalty purchase agreements. If we earn any such payments, they will be accounted for as variable consideration under ASC 606, *Revenue Recognition,* and will be recorded as income when such payments are received.

We evaluated the expected cash flows to XOMA from royalties and milestone payments expected to be earned on XACIATO, Ovaprene and Sildenafil Cream over the period that we expected it would take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements, and determined to allocate the $22.0 million we received from XOMA in connection with entering into the royalty purchase agreements, net of transaction costs of approximately $1.6 million, to the traditional royalty purchase agreement for XACIATO, and none of it to the synthetic royalty purchase agreement for Ovaprene and Sildenafil Cream. The cash flows to XOMA from royalties and milestone payments expected to be earned on Ovaprene and Sildenafil Cream were expected to be de

minimis over the period that we expected it would take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements because, unlike XACIATO, Ovaprene and Sildenafil Cream were not commercial assets at the time the evaluation was made.

We determined that the traditional royalty purchase agreement represented a complete sale of a nonfinancial asset (our right, title and interest in and to future payments related to commercial sales of XACIATO) for which XOMA would bear all benefit and for which we had no obligations or involvement going forward, and therefore should be accounted for within the scope of Accounting Standards Codification ("*ASC") 610-20, Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets*. The $22.0 million net of transaction costs of approximately $1.6 million was recorded as other income on our consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

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 R&D expense, or contra R&D, 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, 2025 and December 31, 2024, there were no material adjustments to our prior period estimates of grant funded research and development expenses. Refer to Note 15 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, 2025 and December 31, 2024 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, 2025 and 2024

The following table summarizes our consolidated results of operations for the years ended December 31, 2025 and 2024, and the change in the applicable line item in terms of dollars and percentage:

	Years Ended December 31,		Change	
	2025	2024	$	%
Revenue				
License fee and other revenue	$ 1,030,193	$ 9,784	$ 1,020,409	10,429 %
Total revenue	1,030,193	9,784	1,020,409	10,429 %
Cost of revenue	295,799	—	295,799	— %
Operating expenses				
Selling, general and administrative expenses	8,763,376	9,156,061	(392,685)	(4)%
Research and development expenses	5,523,352	14,305,208	(8,781,856)	(61)%
Total operating expenses	14,286,728	23,461,269	(9,174,541)	(39)%
Loss from operations	(13,552,334)	(23,451,485)	10,194,950	43 %
Other income (expense)				
Sale of royalty and milestone rights, net	—	20,379,376	(20,379,376)	(100)%
Other income (expense), net	153,060	(981,490)	1,134,550	116 %
Net loss	$ (13,399,274)	$ (4,053,599)	$ (9,345,675)	231 %

Revenues

The approximately $1.0 million increase in license fee and other revenue was primarily attributable to the $1.0 million of revenue recognized upon the termination of the license agreement with Bayer in December 2025.

Cost of revenues

Cost of revenues relates primarily to expenses associated with medical education and awareness related to the commercialization of DARE to PLAY.

Selling, general and administrative expenses

The decrease of approximately $0.4 million in SG&A expenses from 2024 to 2025 was primarily attributable to decreases in (i) stock-based compensation expense of approximately $0.5 million, (ii) personnel costs of approximately $0.3 million due to reduced compensation expense, and (iii) general corporate overhead expenses of approximately $0.3 million. Such decreases were partially offset by increases in commercial-readiness expenses of approximately $0.4 million primarily for DARE to PLAY and professional services expenses of approximately $0.3 million.

Research and development expenses

The following table summarizes our R&D expenses for the periods indicated, together with the changes in those items in terms of dollars and percentage:

	Years Ended December 31,		Change	
	2025	2024	$	%
Direct program costs:				
Ovaprene [1]	$ 5,016,187	$ 8,518,495	$ (3,502,308)	(41)%
Sildenafil Cream [2]	1,143,221	2,361,052	(1,217,831)	(52)%
Other advanced clinical stage programs	2,805,127	1,421,888	1,383,239	97 %
Phase 1 and Phase 1-ready clinical stage programs [1]	1,548,800	761,721	787,079	103 %
Preclinical stage programs [1]	6,365,438	4,233,762	2,131,676	50 %
Other development programs	—	27,542	(27,542)	(100)%
Contra R&D expenses [3]	(13,919,881)	(7,685,533)	(6,234,348)	81 %
Total direct program costs	2,958,892	9,638,927	(6,680,035)	(69)%
Indirect costs:				
Personnel-related (including stock-based compensation)	4,691,957	5,611,057	(919,100)	(16)%
Outside services (including consulting)	21,378	543	20,835	3837 %
Facilities-related (including depreciation)	75,215	78,168	(2,953)	(4)%
Other indirect R&D costs	185,194	176,061	9,133	5 %
Contra R&D expenses	(2,409,284)	(1,199,548)	(1,209,736)	101 %
Total indirect R&D costs	2,564,460	4,666,281	(2,101,821)	(45)%
Total R&D expenses	$ 5,523,352	$ 14,305,208	$ (8,781,856)	(61)%

(1) The applicable program(s) receive grant funding and/or the Tax Incentive. The amount of R&D expense for the period indicated is shown on a gross basis (i.e., without deducting the amount of contra R&D expense for the applicable program(s). See footnote (3) below.

(2) For 2025, the dollar amount also includes expenses for DARE to PLAY.

(3) These contra R&D expenses were recognized as follows for the years ended December 31, 2025 and 2024: (a) Ovaprene, $2.5 million, and $0.2 million, respectively; (b) Other advanced clinical stage programs, $2.9 million and $0, respectively, (c) Phase 1 and Phase 1-ready clinical stage programs, $0.4 million and $1.3 million, respectively; and (d) Preclinical stage programs, $8.1 million and $6.2 million, respectively.

The decrease of approximately $8.8 million in R&D expenses from 2024 to 2025 was primarily attributable to (i) an increase in contra-R&D expenses, (ii) a decrease in manufacturing costs related to Ovaprene, (iii) a decrease in costs related to development activities for Sildenafil Cream, (iv) a decrease in personnel costs, and (v) a decrease in costs related to development activities for DARE-HRT1 partially offset by increases in costs related to development activities for (A) our other advanced clinical stage programs —primarily attributable to our DARE-HPV program, (B) our pre-clinical and other development programs —primarily attributable to our DARE-LARC1 program, and (C) our Phase 1 and Phase 1-ready clinical stage programs —primarily attributable to our DARE-PTB1 program. Contra-R&D expenses for the year ended December 31, 2025 primarily offset direct program costs for DARE-LARC1, DARE-HPV and Ovaprene. Contra R&D expenses for the year ended December 31, 2024 primarily offset direct program costs for DARE-LARC1.

Other income (expense)

Sale of royalty and milestone rights, net

The $20.4 million of other net income for 2024 represents the $22.0 million payment to us in April 2024 under the royalty purchase agreements we entered into with XOMA, net of approximately $1.6 million in transaction costs.

Other income (expense), net

The increase of $1.1 million in other income (expense) for 2025 as compared to 2024 was primarily due to increased interest earned on cash balances in 2025 and the receipt in the current year of approximately $0.3 million of employee retention credits for applications filed during 2023, offset by a loss on the disposal of a fixed asset of $0.6 million in 2024.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

In the near term, we plan to focus primarily on: (a) our ongoing Ovaprene Phase 3 study; (b) executing against our Section 503B compounding and consumer health products business strategies, with a focus on DARE to PLAY, DARE to RECLAIM estradiol progesterone intravaginal ring and DARE to RESTORE vaginal probiotics; and (c) advancing the development of product candidates for which the costs are being supported by non-dilutive grant or other award funding, in particular DARE-LARC1 and DARE-HPV. We will also continue engagement with the FDA to align on the Phase 3 program for Sildenafil Cream and will continue to work on the development of our other clinical and preclinical-stage programs.

At December 31, 2025, we had cash and cash equivalents of approximately $24.7 million and working capital of approximately $3.4 million. We will need additional capital to fund our operating needs through the fourth quarter of 2026 and to meet our current obligations as they become due. Our cash and cash equivalents at December 31, 2025 included funds received under grant agreements that generally may be applied solely toward direct costs for the funded project under those grant agreements other than an approximately 5% to 22% indirect cost allowance, and as of December 31, 2025, our deferred grant funding liability was approximately $19.7 million, substantially all of which consisted of funds intended to support the DARE-LARC1 program, the Ovaprene Phase 3 clinical study, and the DARE-HPV program. For more information about these grant agreements, see "—Contractual Obligations and Other Commitments—Grant Agreements" below, and Note 2 "Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding" and Note 15 "Grant Awards—Other Non-Dilutive Grant Funding" to the accompanying consolidated financial statements.

In addition to our ongoing Regulation A offering, we will continue to evaluate and may pursue various other capital raising options, including sales of equity, debt financings, government or other grant funding, collaborations, structured financings, and commercial collaborations or other strategic transactions. Our ability to obtain additional capital, including through our ongoing Regulation A offering, and the timing and terms thereof, depend on various factors, many aspects of which are not entirely within our control, and there can be no assurance that capital will be available when needed or, if available, on terms favorable to us and our stockholders. 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. If we cannot raise capital when needed, on favorable terms or at all, we will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our product candidate programs and/or reduce expenses.

At December 31, 2025, our accumulated deficit was approximately $188.7 million, and we had a net loss of approximately $13.4 million and negative cash flows from operations of approximately $9.9 million for the year ended December 31, 2025. Because we are in the early stages of executing against our Section 503B compounding and consumer health products business strategies and, as an organization, we have no experience in or infrastructure for commercializing products, both the timing and amount of potential revenue we may generate remain uncertain. As a result, we may continue to incur significant losses from operations and negative cash flows from operations for the next several years, and may never generate sufficient revenues to finance our operations or achieve profitability. Based on our current analysis of the conditions described above, there is substantial doubt about our ability to continue as a going concern within the 12-month period from the issuance date of the accompanying consolidated financial statements. The accompanying consolidated financial statements were prepared on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. 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.

We expect our operating expenses will increase substantially in the future as we continue to develop and seek FDA approval for our product candidates and expand our capabilities to support our 503B compounding and consumer health business strategies. Our future capital requirements are difficult to predict because they will depend on many factors that are highly variable and difficult to predict, including, but not limited to, those discussed in the risk factors in Part I, Item 1A of this report under “Risks Related to Our Financial Position and Capital Needs.”

Capital Resources

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, strategic collaborations and royalty monetization transactions.

We have an ongoing Regulation A offering in which are offering up to 4,854,000 units, each consisting of one share of our Series A convertible preferred stock, which is convertible into two shares of our common stock, and two warrants, each exercisable for one share of our common stock at an exercise price of $4.00 per share. The offering price of each unit is $5.00. As of the date of this report, we have issued an aggregate of 65,640 units to investors in the offering, consisting of 65,640 shares of Series A convertible preferred stock and warrants to purchase up to 131,280 shares of our common stock, for gross proceeds of approximately $328,200.

We have a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, to sell shares of our common stock from time to time through an ATM offering under which Stifel acts as our agent. During 2025, we sold 4,329,116 shares of our common stock under the sales agreement for net proceeds of approximately $17.6 million. Shares of our common stock sold under the sales agreement were offered and sold under our shelf registration statement on Form S-3 (File No. 333-278380), declared effective by the SEC on May 10, 2024. Because the market value of our outstanding shares of common stock held by non-affiliates, or our public float, is less than $75.0 million, our use of a shelf registration statement is currently limited by what is known as the SEC's "baby shelf rule" to one-third of our public float in any 12-month period. Because of the "baby shelf rule" and based on sales of shares of our common stock under our ATM sales agreement, we do not expect to sell any additional shares under our ATM sales agreement during the approximately 12-month period from July 2025, unless and until our public float exceeds approximately $54.0 million, as determined in accordance with SEC rules.

We have a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, under which, subject to the conditions thereof, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million in shares of our common stock. Such sales of our common stock to Lincoln Park, if any, are subject to certain limitations, and may occur from time to time, at our sole discretion, over the 24-month period commencing on November 27, 2024. We sold 1,470,000 shares of our common stock under this purchase agreement during 2025 for net proceeds of approximately $3.1 million. As of the filing date of this report, due to the limitations in the purchase agreement on the number of shares we can sell at an average price of less than $3.59, unless we obtain stockholder approval to do so, we do not expect to sell any more shares to Lincoln Park. See Note 9 "Stockholders' Equity—Equity Line " to the accompanying consolidated financial statements for additional information regarding these limitations.

We expect to begin recording revenue from sales of our 503B products and consumer health products when such products are commercially available for purchase and are shipped. Because we are in the early stages of executing against our Section 503B compounding and consumer health products strategy and, as an organization, we have no experience in or infrastructure for commercializing products, the amount of potential revenue we may generate during 2026 remains uncertain.

Cash Flows

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

	Years Ended December 31,	
	2025	2024
Net cash (used in) provided by operating activities	$ (9,885,870)	$ 5,473,555
Net cash used in investing activities	(385,278)	(573,046)
Net cash provided by financing activities	19,277,144	354,522
Effect of exchange rate changes on cash, cash equivalents and restricted cash	7,186	(67,913)
Net increase in cash, cash equivalents and restricted cash	$ 9,013,182	$ 5,187,118

Net cash used in operating activities

Cash used in operating activities during the year ended December 31, 2025 included the net loss of $13.4 million, decreased by non-cash stock-based compensation expense of approximately $1.5 million. Changes in

operating assets and liabilities included a decrease in deferred revenue of $1.0 million related to revenue recognized during the period for amounts previously received, which reduced operating cash. Components providing operating cash were an increase in deferred grant funding of approximately $3.1 million, a decrease in prepaid expenses of approximately $0.7 million, and an increase in interest payable of approximately $0.6 million related to our royalty interest financing agreement with UiE. Components reducing operating cash were (i) a decrease in accrued expenses of approximately $2.3 million primarily as a result of prior year accruals not present in the current year including a $1.0 million milestone due under a license agreement, approximately $0.5 million related to the construction of capital equipment, and approximately $0.8 million of accrued bonus expense, (ii) an increase in other receivables of approximately $0.3 million, and (iii) a decrease in accounts payable of approximately $0.3 million.

Cash provided by operating activities during the year ended December 31, 2024 included the net loss of $4.1 million, decreased by non-cash stock-based compensation expense of approximately $2.2 million. Components providing operating cash were a decrease in prepaid expenses of approximately $3.6 million, an increase in deferred grant funding of approximately $2.8 million, a decrease in other receivables of approximately $0.7 million, an increase in interest payable of approximately $0.5 million related to our royalty interest financing agreement with UiE, an increase in accrued expenses of $0.2 million, and a decrease in deposits of $0.4 million. Components reducing operating cash were a decrease in accounts payable of approximately $1.9 million and a decrease in other non-current assets of approximately $34,000.

Net cash used in investing activities

Net cash used in investing activities during the years ended December 31, 2025 and December 31, 2024 was related to purchases of property and equipment of approximately $0.4 million and $0.6 million, respectively.

Net cash provided by financing activities

Net cash provided by financing activities during the year ended December 31, 2025 primarily consisted of net proceeds of approximately $17.6 million and $3.1 million from the sale of our common stock under our ATM sales agreement and our equity line arrangement with Lincoln Park, respectively. These proceeds were partially offset by (i) principal payments of approximately $1.3 million related to our finance lease obligation, and (ii) payments of approximately $0.3 million for deferred offering costs associated with our capital-raising activities.

Net cash provided by financing activities during the year ended December 31, 2024 primarily consisted of proceeds from (i) the sale of our common stock under our ATM sales agreement and (ii) the financing of certain director and officer and other liability insurance premiums, partially offset by payments on the insurance financing payable.

Contractual Obligations and Other Commitments

License and Royalty Agreements

We have assembled our pipeline primarily through acquisitions, in-license agreements, and other collaborations. We agreed to make royalty and milestone payments, and in some cases annual license fee payments, under the license and development agreements under which we acquired rights to intellectual property from third parties. For information about these obligations see Note 3 "Strategic Agreements—Strategic Agreements for Pipeline Development" to the accompanying consolidated financial statements. The amount and timing of most of these payments are difficult to predict because the timing of milestone payments for pre-commercial programs generally depends on the progress of and success in development of a particular program, which is subject to many risks and uncertainties as discussed elsewhere in this report and difficult to predict, and the timing and amount of royalty and milestone payments related to commercial products generally depends on their commercial success, which may, as it is with XACIATO, be out of our control.

During 2026, based on our current expectations regarding the progress of development of our product candidates and sales of XACIATO and DARE to PLAY, we expect such payments to upstream licensors to be immaterial. With respect to our license agreement relating to XACIATO, royalties payable by us to upstream licensors will be funded by royalty payments made by our licensee, Organon. For further discussion of these potential payments, see Note 3 "Strategic Agreements—Strategic Agreements for Pipeline Development" to the accompanying consolidated financial statements. With respect to DARE to PLAY, for at least the first twelve months following its market introduction, we anticipate a mid single-digit royalty payment obligation to our upstream licensor on annual net sales.

Grant Agreements

For information regarding our grant agreements with the Foundation, see "--Deferred Grant Funding," above, and Note 2, "Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding" and Note 15, "Grant Awards-Other Non-Dilutive Grant Funding" to the accompanying consolidated financial statements.

Royalty Purchase Agreements with XOMA

In April 2024, we entered into a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA pursuant to which, among other things, we sold our right, title and interest in the following to XOMA: (a) all of the royalties and potential milestone payments we would otherwise have the right to receive from and after April 1, 2024 under our exclusive license agreement with Organon based on net sales of XACIATO, net of our obligations to upstream licensors and UiE; and (b) a portion of future net sales of Ovaprene, Sildenafil Cream and DARE to PLAY.

For more information regarding our contractual obligations to XOMA, see ITEM 1. “BUSINESS— Royalty Monetization Transactions—Traditional and Synthetic Royalty Purchase Agreements with XOMA” in Part I of this report and Note 13 “Royalty Purchase Agreements” to the accompanying consolidated financial statements.

Royalty Interest Financing Agreement

In December 2023, we entered into a royalty interest financing agreement with UiE pursuant to which we sold to UiE an interest in the royalty and milestone payments we are entitled to receive in respect of net sales of XACIATO under our license agreement with Organon. In exchange for any payments to us from UiE under the agreement, we agreed to make payments to UiE out of royalty and milestone payments earned on net sales of XACIATO from Organon, net of our obligations to upstream licensors, until UiE receives a specified return on its investment, or using our other sources of assets or income to complete such payments if UiE has not received the specified return on its investment by the end of 2035. We have the right to make prepayments on or pay in full and retire all of our payment obligations to UiE.

For more information regarding our contractual obligations to UiE, see ITEM 1. “BUSINESS— Royalty Monetization Transactions—Royalty Interest Financing Agreement” in Part I of this report and Note 12 “Royalty Interest Financing” to the accompanying consolidated financial statements.

Leases

We have two operating leases for our laboratory and office spaces that each expire in 2027. As of December 31, 2025, we had future minimum lease payments under these leases of $1.2 million, $0.6 million of which is classified as current and $0.6 million of which is classified as long-term, the remainder of which represents future interest payments. We have one finance lease for our clean room space that expires in 2026. As of December 31, 2025, we had future minimum lease payments under this lease of $1.5 million, all of which is classified as current, the remainder of which represents future interest payments. For additional information on our lease obligations, See Note 11 "Leases" 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, and with Section 503B-registered outsourcing facilities, dispensing pharmacies, telehealth providers, and other third parties to help bring our proprietary formulations to market. These contracts generally provide for termination upon notice, and we do not believe that our non-cancelable obligations under these agreements are material.

For descriptions of additional contractual obligations and commitments, see Note 14 “Commitments and Contingencies” to the accompanying consolidated financial statements.

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, 2025 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, 2025 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, 2025 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, 2025 to December 31, 2025, 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 2026 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 2026 Proxy Statement and is incorporated in this report by reference, except as to information disclosed in the 2026 Proxy Statement pursuant to Item 402(v) of Regulation S-K relating to pay versus performance.

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 2026 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 2026 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 2026 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	08/12/2024	3.1	
3.2	Third Amended and Restated By-Laws (as amended through January 24, 2023)	10-Q	001-36395	5/14/2024	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	10-K	001-36395	03/28/2024	4.4	
4.5	Description of securities of the registrant					X
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	001-36395	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	

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+	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	
10.9+	License Agreement dated as of August 12, 2023 between Douglas Pharmaceuticals Limited and Daré Bioscience, Inc.	10-K	001-36395	03/31/2025	10.10	
10.10+	Grant Agreement between Daré Bioscience, Inc. and the Bill & Melinda Gates Foundation effective as of June 30, 2021, as amended to date					X
10.11+	Grant Agreement between Daré Bioscience, Inc. and the Bill & Melinda Gates Foundation effective as of November 11, 2024, as amended to date	10-K	001-36395	03/31/2025	10.12	
10.12+	Subaward Agreement between the Consortium Management Firm, National Collegiate Inventors and Innovators Alliance, Inc. d/b/a/ VentureWell and Daré Bioscience, Inc., effective as of October 12, 2024	10-K	001-36395	03/31/2025	10.13	
10.13	Royalty Interest Financing Agreement entered into as of December 21, 2023 between Dare Bioscience, Inc. and United in Endeavor, LLC	10-K	001-36395	03/28/2024	10.12	
10.14	Purchase Agreement, dated October 21, 2024, by and between Daré Bioscience, Inc. and Lincoln Park Capital Fund, LLC	8-K	001-36395	10/21/2024	10.1	
10.15	Registration Rights Agreement, dated October 21, 2024, by and between Daré Bioscience, Inc. and Lincoln Park Capital Fund, LLC	8-K	001-36395	10/21/2024	10.2	
10.16+	Traditional Royalty Purchase Agreement between Daré Bioscience, Inc. and XOMA (US) LLC, dated as of April 29, 2024	10-Q	001-36395	08/12/2024	10.1	

10.17+	Synthetic Royalty Purchase Agreement between Daré Bioscience, Inc. and XOMA (US) LLC, dated as of April 29, 2024	10-Q	001-36395	08/12/2024	10.2
MANAGEMENT CONTRACTS AND COMPENSATORY PLANS					
10.18(a)*	Daré Bioscience, Inc. Amended and Restated 2014 Stock Incentive Plan	8-K	001-36395	7/12/2018	10.1
10.18(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
10.18(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
10.19(a)*	Daré Bioscience, Inc. 2022 Stock Incentive Plan	10-Q	001-36395	8/12/2024	10.7
10.19(b)*	Amendment No. 1 to Daré Bioscience, Inc. 2022 Stock Incentive Plan	8-K	001-36395	7/9/2025	10.1
10.19(c)*	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)
10.19(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)
10.20*	Daré Bioscience, Inc. Performance Bonus Plan, as amended	10-Q	001-36395	11/9/2023	10.3
10.21*	Form of indemnification agreement between the registrant and each of its executive officers and directors	S-1	333-194442	03/10/2014	10.16
10.22*	Amended and Restated Non-Employee Director Compensation Policy (as amended through January 28, 2025)	10-Q	001-36395	05/13/2025	10.10
10.23(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
10.23(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)

10.23(c)*	Amendment No. 2 to Employment Agreement between Daré Bioscience, Inc. and Sabrina Martucci Johnson, dated as of May 20, 2024	10-Q	001-36395	08/12/2024	10.5	
10.24*	Daré Bioscience, Inc. Change in Control Policy (as amended on April 29, 2024)	10-Q	333-251599	08/12/2024	10.6	
OTHER EXHIBITS						
19.1	Daré Bioscience, Inc. Amended and Restated Insider Trading Policy (October 22, 2024)	10-K	001-36395	03/31/2025	19.1	
21.1	Subsidiaries of the registrant					X
23.1	Consent of Haskell & White LLP					X
23.2	Consent of Haskell & White LLP					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	10-K	001-36395	03/28/2024	99.7	
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 26, 2026

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

Signature	Title	Date
/s/ SABRINA MARTUCCI JOHNSON Sabrina Martucci Johnson	President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer) and Director	March 26, 2026
/s/ MARDEE HARING-LAYTON MarDee Haring-Layton	Chief Accounting Officer (Principal Accounting Officer)	March 26, 2026
/s/ WILLIAM H. RASTETTER William H. Rastetter, Ph.D.	Chairman of the Board and Director	March 26, 2026
/s/ JESSICA D. GROSSMAN Jessica D. Grossman, M.D.	Director	March 26, 2026
/s/ SUSAN L. KELLEY Susan L. Kelley, M.D.	Director	March 26, 2026
/s/ GREGORY W. MATZ Gregory W. Matz, CPA	Director	March 26, 2026
/s/ ROBIN STEELE Robin Steele, J.D., L.L.M.	Director	March 26, 2026

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 sheets of Daré Bioscience, Inc. and Subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2025, 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, 2025 and 2024, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, 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 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated 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 consolidated 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 26, 2026

Daré Bioscience, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31,	
	2025	2024
Assets		
Current Assets		
Cash and cash equivalents	$ 24,711,356	$ 15,698,174
Prepaid expenses and other current assets	2,352,523	2,749,689
Total current assets	27,063,879	18,447,863
Property and equipment, net	1,558,890	1,335,732
Operating lease right-of-use assets	1,097,580	1,206,942
Finance lease right-of-use assets	1,744,775	—
Other non-current assets	1,009,439	1,110,594
Total assets	$ 32,474,563	$ 22,101,131
Liabilities and stockholders' equity (deficit)		
Current Liabilities		
Accounts payable	$ 1,200,686	$ 1,455,832
Accrued expenses	725,184	3,042,918
Deferred grant funding	19,651,452	16,561,625
Current portion of liability related to sale of future royalties	11,711	4,054
Current portion of lease liabilities (operating)	602,552	548,638
Current portion of lease liabilities (finance)	1,494,102	—
Total current liabilities	23,685,687	21,613,067
Deferred revenue, non-current	—	1,000,000
Liability related to the sale of future royalties, net	5,386,877	4,745,770
Lease liabilities long term (operating)	559,365	754,383
Total liabilities	29,631,929	28,113,220
Commitments and contingencies (Note 14)		
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, 14,499,502 and 8,700,386 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	1,450	870
Additional paid-in capital	191,951,711	169,705,480
Accumulated other comprehensive loss	(421,623)	(428,809)
Accumulated deficit	(188,688,904)	(175,289,630)
Total stockholders' equity (deficit)	2,842,634	(6,012,089)
Total liabilities and stockholders' equity (deficit)	$ 32,474,563	$ 22,101,131

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2025	2024
Revenue		
License fee revenue and other revenue	$ 1,030,193	$ 9,784
Total revenue	1,030,193	9,784
Cost of revenues	295,799	—
Operating expenses		
Selling, general and administrative	8,763,376	9,156,061
Research and development	5,523,352	14,305,208
Total operating expenses	14,286,728	23,461,269
Loss from operations	(13,552,334)	(23,451,485)
Other income (expense)		
Sale of royalty and milestone rights, net of transaction costs (Note 13)	—	20,379,376
Other income (expense)	153,060	(981,490)
Net loss	$ (13,399,274)	$ (4,053,599)
Net loss to common stockholders	$ (13,399,274)	$ (4,053,599)
Foreign currency translation adjustments	7,186	(67,913)
Comprehensive loss	$ (13,392,088)	$ (4,121,512)
Loss per common share - basic and diluted	$ (1.20)	$ (0.48)
Weighted average number of common shares outstanding:		
Basic and diluted	11,178,752	8,497,459

See accompanying notes to the consolidated financial statements.

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

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity (deficit)
Balance at December 31, 2023	**8,331,161**	**$ 833**	**$ 166,548,454**	**$ (360,896)**	**$ (171,236,031)**	**$ (5,047,640)**
Stock-based compensation	—	—	2,203,257	—	—	2,203,257
Issuance cost on equity line paid in common stock	137,614	14	500,213	—	—	500,227
Issuance of common stock, net of issuance costs	109,655	11	453,568	—	—	453,579
Reverse stock split adjustment	121,956	12	(12)	—	—	—
Net loss	—	—	—	—	(4,053,599)	(4,053,599)
Foreign currency translation adjustments	—	—	—	(67,913)	—	(67,913)
Balance at December 31, 2024	8,700,386	$ 870	$ 169,705,480	$ (428,809)	$ (175,289,630)	$ (6,012,089)
Stock-based compensation	—	—	1,496,562	—	—	1,496,562
Issuance of common stock, net of issuance costs	5,799,116	580	20,749,669	—	—	20,750,249
Net loss	—	—	—	—	(13,399,274)	(13,399,274)
Foreign currency translation adjustments	—	—	—	7,186	—	7,186
Balance at December 31, 2025	**14,499,502**	**$ 1,450**	**$ 191,951,711**	**$ (421,623)**	**$ (188,688,904)**	**$ 2,842,634**

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (13,399,274)	$ (4,053,599)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,634,486	42,325
Right-of-use asset - operating lease	516,895	471,003
Stock-based compensation expense	1,496,562	2,203,256
Loss on disposal of property and equipment	—	600,000
Non-cash royalty revenue related to sale of future royalties	(6,298)	202
Non-cash interest expense	82,502	317,318
Changes in operating assets and liabilities:		
Accounts receivable	(12,053)	—
Other receivables	(331,026)	719,229
Prepaid expenses	668,486	3,598,565
Deposits	—	402,414
Other current assets	(65,405)	—
Other non-current assets	(78,723)	45,562
Operating lease liability	(548,638)	(459,763)
Accounts payable	(255,146)	(1,929,717)
Accrued expenses	(2,250,627)	171,473
Interest payable	572,561	520,816
Deferred grant funding	3,089,828	2,824,471
Deferred revenue	(1,000,000)	—
Net cash (used in) provided by operating activities	(9,885,870)	5,473,555
Cash flows from investing activities		
Purchases of property and equipment	(385,278)	(573,046)
Net cash used in investing activities	(385,278)	(573,046)
Cash flows from financing activities		
Net proceeds from issuance of common stock	20,930,126	453,579
Payments of deferred offering costs	(321,686)	(79,308)
Repayment of liability on sale of future royalties	—	(2,189)
Issuance of note payable	486,721	561,663
Payments on note payable	(553,829)	(579,223)
Principal payments on finance lease	(1,264,188)	—
Net cash provided by financing activities	19,277,144	354,522
Effect of exchange rate changes on cash and cash equivalents and restricted cash	7,186	(67,913)
Net change in cash, cash equivalents and restricted cash	9,013,182	5,187,118
Cash, cash equivalents and restricted cash, beginning of year	15,998,174	10,811,056
Cash, cash equivalents and restricted cash, end of year	$ 25,011,356	$ 15,998,174
Reconciliation of cash, cash equivalents and restricted cash to amounts reported in the consolidated balance sheets:		
Cash and cash equivalents	$ 24,711,356	$ 15,698,174
Restricted cash included in other non-current assets	300,000	300,000
Total cash, cash equivalents and restricted cash	$ 25,011,356	$ 15,998,174
Supplemental disclosure of non-cash investing and financing activities:		
Remeasurement of operating lease right-of-use assets and lease liabilities due to lease modification	$ 407,534	$ 358,315
Finance right-of-use assets obtained in exchange for new finance lease liabilities	$ 2,841,027	$ —
Remeasurement of finance lease right-of-use assets and lease liabilities due to lease modification	$ 82,736	$ —

Prepaid rent reclassified to finance lease right-of-use asset	$	458,850	$	—
Deferred issuance costs applied from prepayments made in the prior year	$	179,877	$	—
Issuance cost on equity paid in common stock	$	—	$	500,227
Additions to property and equipment and reduction of deposits	$	—	$	749,036

See accompanying notes to the consolidated financial statements.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Daré Bioscience, Inc. is a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real solutions. Daré Bioscience, Inc. and its wholly-owned subsidiaries operate in one segment. In this report, the “Company” refers collectively to Daré Bioscience, Inc. and its wholly-owned subsidiaries, unless otherwise stated or the context otherwise requires.

The Company began assembling its diverse portfolio of assets in 2017 through acquisitions, exclusive in-licenses and other collaborations. The Company's programs target unmet needs in women's health, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease, vaginal health and menopause, and aim to enhance outcomes and convenience.

The Company’s operations have historically focused on research and development activities to advance its product candidates through clinical development and regulatory approval. While research and development remain an important part of the Company's strategy, the Company announced in March 2025 an expansion of its business model to include a dual-path approach to bringing new products to market. For select proprietary formulations, the Company is pursuing both traditional FDA approval and earlier market access via outsourcing facilities registered under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), which may compound and distribute certain drugs without patient-specific prescriptions. This dual-path approach reflects a shift in the Company’s operational priorities and resource allocation toward commercial execution, including partnerships and product distribution via Section 503B outsourcing facilities and select consumer health channels. The Company uses the term "Section 503B compounding" to refer to the production and supply of compounded drugs by outsourcing facilities registered under Section 503B of the FDCA without patient-specific prescriptions in accordance with Section 503B of the FDCA. In addition to prescription-based offerings — both products approved by the U.S. Food and Drug Administration (FDA) and compounded drugs— the Company intends to bring to market select consumer health products that do not require a physician’s prescription.

The Company's portfolio of product candidates includes drug and drug/device product candidates and potential product candidates in various stages of development, from preclinical through a Phase 3 clinical study, and will require review and approval from the FDA or a comparable foreign regulatory authority, prior to being marketed and sold.

The first FDA-approved product to emerge from the Company's portfolio is XACIATO® (clindamycin phosphate) vaginal gel 2%, or XACIATO. In 2022, the Company licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO to an affiliate of Organon & Co., Organon International GmbH, or Organon. In January 2024, Organon announced that XACIATO was available nationwide in the U.S. In April 2024, the Company sold its rights to all royalty and potential milestone payments based on net sales of XACIATO under its agreement with Organon, net of its obligations to certain third parties, to XOMA (US) LLC, or XOMA, until XOMA receives a specified return on its investment, after which the Company will share equally in the royalty and milestone payments earned on net sales of XACIATO from Organon.

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.

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.

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 arrangements, 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.

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.

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, net losses and negative cash flows from operations and expects significant losses from operations, net losses and negative cash flows from operations 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 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 the Company's ability to continue as a going concern.

At December 31, 2025, the Company had cash and cash equivalents of approximately $24.7 million and working capital of approximately $3.4 million. The Company's cash and cash equivalents at December 31, 2025 includes funds received under grant agreements that may be applied solely toward direct costs for the funded projects under those grant agreements, other than an approximately 5% to 22% indirect cost allowance, and as of December 31, 2025, the Company's deferred grant funding liability was approximately $19.7 million. See Note 15 Grant Awards.

The Company will require additional capital to advance the development programs in its pipeline that are not currently being supported by non-dilutive grant or other funding, to enable further investment across its entire portfolio of product candidates, and to support its operating plans. The Company is currently seeking to raise capital under its Regulation A offering (see Note 17 Subsequent Events) and will continue to evaluate and may pursue various other capital raising options, including sales of equity, debt financings, government or other grant funding, collaborations, structured financings, and commercial collaborations or other strategic transactions. The Company’s ability to obtain additional capital, including through its ongoing Regulation A offering, and the timing and terms thereof, depend on various factors, many aspects of which are not entirely within its control, and there can be no assurance that capital will be available when needed or, if available, on terms favorable to the Company and its stockholders. Raising additional capital may cause substantial dilution to the Company’s stockholders, restrict its operations or require it to relinquish rights in its technologies or product candidates and their future revenue streams. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its product candidate programs and/or reduce expenses.

The Company has a history of losses from operations, net losses and negative cash flows from operations. At December 31, 2025, the Company had an accumulated deficit of approximately $188.7 million and the Company incurred a net loss of approximately $13.4 million and had negative cash flow from operations of approximately $9.9 million for the year ended December 31, 2025. Because the Company is in the early stages of executing against its Section 503B compounding and consumer health products business strategies and, as an organization, the Company has no experience in or infrastructure for commercializing products, both the timing and amount of potential revenue the Company may generate remain uncertain. As a result, the Company may continue to incur significant losses from operations and negative cash flows from operations for the next several years, and may never generate sufficient revenues to finance its operations or achieve profitability. Based on the Company’s current analysis of the conditions described above, there is substantial doubt about the Company's ability to continue as a going concern within the 12

month period from the issuance date of the accompanying consolidated financial statements. The accompanying consolidated financial statements were prepared 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 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.

Segment Information

Operating segments are defined as components of an enterprise about which discrete financial information is available for evaluation by the Chief Operating Decision Maker, or CODM, or decision-making group in making decisions on how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, or CEO. The CEO views the Company's operations and manages its business as one reportable and operating segment, Women's Health. See Note 16, "Segment Information," for additional information.

Reverse Stock Split

The Company effected a 1-for-12 reverse split of its issued common stock on July 1, 2024. At the effective time of the reverse stock split, every 12 shares of the Company’s common stock was automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split did not change the number of authorized shares or the par value per share of the Company’s common stock. See Note 9, Stockholders' Equity, for additional information regarding the reverse stock split.

All common stock share and per share data presented in the accompanying consolidated financial statements have been retroactively adjusted to reflect the impact of the reverse stock split for all periods presented, without giving effect to whole shares issued in lieu of fractional shares. In addition, proportionate adjustments were made in accordance with the applicable terms of outstanding stock options and warrants, the Company’s stock incentive plans and an existing agreement to the (a) per share exercise prices of, and the number of shares underlying, the Company’s outstanding stock options, (b) number of shares available for the grant of awards under the Company’s stock incentive plans, and (c) per share exercise prices of, and the number of shares underlying, outstanding warrants to purchase shares of the Company’s common stock and warrants potentially issuable by the Company in its sole discretion pursuant to an existing agreement.

Significant Accounting Policies

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 $12.0 million in license fee revenue, $10.0 million of which represents the upfront payment under its license agreement for XACIATO, $1.0 million of which represents the payment required by the first amendment to such license agreement entered into in July 2023, and $1.0 million of which represents the license fee revenue recognized upon the termination of a license agreement in December 2025 (see Bayer License, below).

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 $26,000 in royalty revenue.

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 was recorded as deferred license revenue in the Company's consolidated balance sheets at December 31, 2024. Bayer, in its sole discretion, had 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. In November 2025, the Company received notice from Bayer that it was terminating the license agreement. The Company and Bayer mutually agreed to terminate the agreement effective as of December 2, 2025 and the $1.0 million upfront payment was recognized as license fee revenue on such date.

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.

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

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.

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, 2025 and 2024, the Company did not incur any research and development expenses that it believes are eligible for the Tax Incentive.

Grant Funding

The Company receives certain research and development funding through grants issued by a division of the National Institutes of Health and the 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 and comprehensive loss 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, 2025 and December 31, 2024, the Company recognized approximately $16.4 million and $8.8 million, respectively, in the statements of operations and comprehensive loss 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.

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. Compensation expense is recognized in the consolidated statements of operations and comprehensive loss on a straight-line basis over the requisite service period of the award. Forfeitures are accounted for in the period they occur. The Company uses the Black-Scholes Pricing Model to determine the fair value of each of the awards which considers factors such as the fair value of the Company's common stock, which is measured as the closing price of the Company's common stock on the date of the grant, the expected term, the volatility of the Company's common stock, risk free interest rate, and dividend yield. Due to the limited number of option exercises, 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, 2025 and 2024, the Company did not record any liabilities for uncertain tax positions.

During each of 2025 and 2024, the Company recorded no provision for income taxes. Management evaluated the Company’s tax positions and, as of December 31, 2025 and 2024, the Company had approximately $3.1 million and $2.9 million of unrecognized benefits, respectively. The tax years 2022 to 2024 and 2021 to 2024 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. The Company is not currently under examination.

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, 2025 and December 31, 2024. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) or using unobservable inputs (Level 3) as of December 31, 2025 or December 31, 2024.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at December 31, 2025				
Current assets:				
Cash equivalents [1]	$ 24,356,333	$ —	$ —	$ 24,356,333
Balance at December 31, 2024				
Current assets:				
Cash equivalents [1]	$ 15,283,784	$ —	$ —	$ 15,283,784

[1] Represents cash held in money market funds.

The carrying amounts of all prepaid expenses and other current assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. In addition, the carrying value of the liability related to the sale of future royalties approximates its fair value as of December 31, 2025, and is based on the Company's current estimate of future royalties expected to be earned over the estimated life of the royalty interest financing arrangement. See Note 12 for the description of the Level 3 inputs used to estimate the carrying value of the liability.

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, 2025 and 2024 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 sheets.

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.

Warrants

The Company performs an assessment of warrants upon issuance to determine their proper classification in the financial statements based upon the warrant's specific terms, in accordance with the authoritative guidance provided in ASC 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity ("ASC 815-40"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480 and whether the warrants meet all of the requirements for equity classification under ASC 815-40, including whether the warrants are indexed in the Company's own Common Stock and whether the warrant holders could potentially require cash settlement of the warrants.

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability-classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter.

Sale of Future Payments

On April 29, 2024, the Company entered into and closed a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA pursuant to which the Company sold its right, title and interest in the following to XOMA (i) all future net royalty and potential net milestone payments the Company would otherwise receive from Organon based on net sales of XACIATO, (ii) a portion of future net sales of Ovaprene and a portion of the $20.0 million payment that the Company could have potentially received under its since terminated license agreement with Bayer relating to Ovaprene, and (iii) a portion of future net sales of Sildenafil Cream. The Company received $22.0 million from XOMA in connection with entering into the royalty purchase agreements. Under the terms of the royalty purchase agreements, if XOMA receives total payments under the royalty purchase agreements equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to the Company for each successive $22.0 million XOMA receives under the royalty purchase agreements. If the Company earns any such payments, they will be accounted for as variable consideration under ASC 606, *Revenue Recognition,* and will be recorded as income when such payments are received. See Note 13, Royalty Purchase Agreements, for additional information regarding the terms of the royalty purchase agreements.

The Company evaluated the expected cash flows to XOMA from royalties and milestone payments expected to be earned on XACIATO, Ovaprene and Sildenafil Cream over the period that the Company expected it would take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements, and determined to allocate the $22.0 million it received from XOMA in connection with entering into the royalty purchase agreements, net of transaction costs of approximately $1.6 million, to the traditional royalty purchase agreement for XACIATO, and none of it to the synthetic royalty purchase agreement for Ovaprene and Sildenafil Cream. The cash flows to XOMA from royalties and milestone payments expected to be earned on Ovaprene and Sildenafil Cream were expected to be de minimis over the period that the Company expected it would take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements because, unlike XACIATO, Ovaprene and Sildenafil Cream were still in development stage and not commercial assets at the time the evaluation was made.

The Company determined that the traditional royalty purchase agreement represented a complete sale of a nonfinancial asset (the Company's right, title and interest in and to future payments related to commercial sales of XACIATO) for which XOMA would bear all benefit and for which the Company had no obligations or involvement going forward, and therefore should be accounted for within the scope of ASC 610-20, Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets. The $22.0 million net of transaction costs of approximately $1.6 million, was recorded as other income on the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

Liability Related to the Sale of Future Royalties

In December 2023, the Company entered into a royalty interest financing agreement with United in Endeavor, LLC or UiE, pursuant to which the Company sold to UiE an interest in royalty and milestone payments the Company receives based on net sales of XACIATO. The Company received $5.0 million from UiE 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 UiE until such time that UiE 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 Company's 2023 consolidated balance sheets as the warrants were deemed to be equity classified.

Deferred Offering Costs

The Company capitalizes certain legal, professional, and other-third party charges related to its efforts to raise capital and other ongoing equity financings as deferred offering costs until fully consummated. These costs are deferred until the completion of the offerings at which time they are reclassified to additional paid-in-capital as a reduction of the offering proceeds. If the Company terminates the planned offering, all of the deferred offering costs will be immediately written off to operating expenses. In October 2024, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, under which the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million of shares of the Company's common stock. Deferred offering costs associated with the financing arrangement with Lincoln Park are reclassified to additional paid in capital on a pro-rata basis over the term of the purchase agreement. In March 2023, the Company entered into a sales agreement to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program. Deferred offering costs associated with the ATM equity offering program are reclassified to additional paid in capital on a pro-rata basis. In December 2025, the Company filed an offering statement on Form 1-A for the sale of preferred stock and warrants in a Regulation A offering. Deferred offering costs associated with this offering are reclassified to additional paid in capital on a pro-rata basis. As of December 31, 2025 and 2024, $0.9 million and $0.7 million of deferred offering costs were capitalized on the balance sheet, respectively.

Leases

The Company determines if an arrangement is a lease at inception. Right-of-use, or ROU, assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligations to make lease payments arising from the lease.

The Company has both operating leases for office facilities and a finance lease for laboratory space. ROU assets and liabilities 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 assets also include any lease prepayments made and exclude 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. The Company elected the practical expedient, which allows the Company to not allocate consideration between lease and non-lease components. In addition, the Company elected the practical expedient such that it does not recognize ROU assets or lease liabilities for leases with a term of 12 months or less. Variable lease payments are recognized in the period in which the obligations for those payments are incurred. Operating lease expense for lease payments is recognized on a straight-line basis over the lease term, while the finance lease results in recognition of amortization expense for the ROU asset and interest expense on the lease liability.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally five years. Repair and maintenance costs are charged to expense as incurred.

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 selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and right-of-use assets. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate, including its eventual residual value. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds its fair value. The Company did not recognize any impairment losses for either of the years ended December 31, 2025 or 2024. The Company recorded a loss on the disposal of a fixed asset of $0.6 million for the year ended December 31, 2024. No such losses were recorded during the year ended December 31, 2025.

Risks and Uncertainties

The Company will require approvals from the FDA, or foreign regulatory agencies prior to being able to sell any products, other than compounded drugs under Section 503B of the FDCA and consumer health products that do not require a physician's prescription. 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 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 and product liability. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

Net Loss Per Share

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

There were stock options exercisable into 1,409,042 and 883,334 shares of common stock outstanding at December 31, 2025 and 2024, respectively. There were warrants exercisable into 1,268,572 shares of common stock outstanding at each of the years ended December 31, 2025 and 2024. 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.

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, 2025, 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, 2025 and 2024, no amounts have been accrued related to such indemnification provisions.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 with early adoption permitted. The Company adopted ASU 2023-09, on a prospective basis, on January 1, 2025, which adoption only impacted the Company's footnote disclosures with no impact on the Company's results of operations or financial condition. See Note 8, Income Taxes, for disclosures related to the adoption of ASU 2023-09.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses. ASU 2024-3 requires new financial statement disclosures in tabular format, disaggregating information about prescribed categories underlying any relevant income statement expense captions. Additionally, in January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. The standard provides guidance to expand disclosures related to the disaggregation of income statement expenses. The standard requires, in the notes to the financial statements, disclosure of specified information about certain costs and expenses, which includes purchases of inventory, employee compensation, depreciation and intangible asset amortization included in each relevant expense caption. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027, on a retrospective or prospective basis, with early adoption permitted. The Company is assessing the guidance, noting the adoption impacts disclosure only.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities, which establishes authoritative guidance on the recognition, measurement, presentation, and disclosure of government grants. Under ASU 2025-10, government grants are recognized when it is probable that the entity will both comply with the conditions of the grant and the grant will be received. The ASU provides specific accounting models for grants related to assets and grants related to income, including options to recognize government grants as deferred income or as a reduction of the asset’s cost basis. The ASU also requires enhanced disclosures regarding the nature of government grants, significant terms and conditions, accounting policies applied, and amounts recognized in the financial statements. ASU 2025-10 is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-10 on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements, which clarifies the guidance in Topic 270 to improve the consistency of interim financial reporting. The ASU provides a comprehensive list of required interim disclosures and introduces a disclosure principle requiring entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-11 on its consolidated financial statements and related disclosures.

The Company does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the consolidated financial statements.

3. STRATEGIC AGREEMENTS

Strategic Agreements for Product Commercialization

Organon Exclusive License Agreement

In 2022, the Company entered into an exclusive license agreement with Organon, 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. As of December 31, 2025, the Company has received a total of $12.8 million in non-refundable payments, all of which have been recorded as license fee revenue in historical periods.

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. As a result of a $1.0 million payment in connection with the license agreement amendment and a $1.8 million milestone payment, both of which occurred in 2023, the transaction price was $12.8 million as of December 31, 2025.

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). Generally, because sales-based payments are required to be paid more than 45 days after the end of each quarter, other than with respect to the fourth quarter, the Company estimates sales-based payments it will recognize for a particular quarter based on an analysis of historical experience and the Company's estimated gross sales and customary deductions for the applicable quarter. To date, it has been challenging for the Company to accurately estimate the amount of the sales-based payments for a particular quarter due to limited historical information available to the Company to inform such estimates. Differences between actual and estimated sales-based payments will be adjusted for in the quarter in which the actual amount becomes known, which is generally expected to be the following quarter.

Refer to Note 13, Royalty Purchase Agreements, regarding the Company's sale to XOMA of all the Company's right, title and interest in and to, from and after April 1, 2024, all net royalty and potential net milestone payments from Organon based on net sales of XACIATO.

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.

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. In November 2025, the Company received notice from Bayer that it was terminating the license agreement. The Company and Bayer mutually agreed to terminate the agreement effective as of December 2, 2025.

In connection with entering into the license agreement, the Company received a $1.0 million upfront non-refundable license fee payment from Bayer, which was recorded as license revenue when the agreement was terminated. See Note 2. Significant Accounting Policies—Revenue Recognition—Bayer License, above.

Strategic Agreements for Pipeline Development

Theramex Co-Development and Licensing Agreement

In February 2025, the Company entered into a co-development and licensing agreement with Theramex for a potential first-in-category biodegradable contraceptive implant called Casea S recently acquired by Theramex. Under the agreement, the Company received a royalty-free, exclusive, fully paid up, sublicensable license to the U.S. patents Theramex recently acquired for Casea S. The license fee paid by the Company during the first quarter of 2025 was recorded as research and development expense. Given that the product is in an ongoing Phase 1 study funded by a grant, there are no development costs for the Company or Theramex at this time. If the Company determines that the results from the study are positive, it would be responsible for conducting a Phase II study in the U.S., and funding for such study and for a future Phase III study in the U.S. will be shared by the Company and Theramex on terms to be agreed upon by the parties, taking into account the size of the opportunity for Casea S in the respective markets.

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 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. As a result of this license, the Company commenced its DARE-HPV program. 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, 2025, 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. As a result of this license, the Company commenced its DARE-GML program. 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, 2025, 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 and the drug delivery technology underlying DARE-LARC1 is now known as the Company's intelligent drug delivery system platform, DARE-IDDS.

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 2021, a total of $1.25 million of the contingent consideration became payable, $75,000 of which was paid in cash and the balance of which was paid in shares of the Company's common stock, as permitted by the terms of the merger agreement. As of December 31, 2025, no additional payments have been made under this agreement.

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 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 had been paid as of December 31, 2025.

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. As of December 31, 2025, no payments have been made under this agreement.

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. As a result of this license agreement, the Company commenced its DARE-HRT1, DARE-FRT1 and DARE-PTB1 programs. 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 had been paid as of December 31, 2025; 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. As of December 31, 2025, no such payments have been made under this agreement.

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. As of December 31, 2025, $1.0 million has been paid under this agreement, which was paid in February 2025.

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, and (b) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones. As of December 31, 2025, $1.2 million in milestone payments have been paid.

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 AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2025	2024
Prepaid clinical expense	$ 718,537	$ 1,290,605
Prepaid development expense	58,750	663,723
Prepaid insurance expense	408,103	398,950
Prepaid legal and professional expenses	206,981	166,429
Deferred offering costs	321,686	—
Other current assets	65,405	—
Other receivables	573,061	229,982
Total prepaid expenses and other current assets	$ 2,352,523	$ 2,749,689

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consist of the following:

	As of December 31,	
	2025	2024
Assets under construction	$ —	$ 1,229,165
IT equipment	47,927	37,239
Leasehold improvements	40,284	40,284
Lab equipment	1,808,692	204,938
	$ 1,896,903	$ 1,511,626
Less– accumulated depreciation	(338,013)	(175,894)
Property and equipment, net	$ 1,558,890	$ 1,335,732

Depreciation expense was approximately $162,000 and $42,000 for the years ended December 31, 2025 and 2024, respectively.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2025	2024
Accrued compensation and benefits	$ 10,261	$ 805,612
Accrued development expense	447,466	1,258,435
Insurance financing payable	182,521	249,628
Other accruals	18,270	662,576
Accrued license fee expense	66,666	66,667
Total accrued expenses	$ 725,184	$ 3,042,918

7. VENDOR CONCENTRATION

The Company had five major vendors that accounted for approximately 27%, 20%, 17%, 16% and 10% of the Company's research and development expenses for the year ended December 31, 2025, and 3%, 2%, 0%, 2% and 6% of the Company's research and development expenditures for the year ended December 31, 2024. The same vendors accounted for 7% and 3% of the Company's total accounts payable and accrued expenses as of each of December 31, 2025 and 2024, respectively. The Company continues to maintain its relationship with these vendors and anticipates incurring significant expenses with these vendors over the next 12 months.

8. INCOME TAXES

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

	Years Ended December 31,	
	2025	2024
Domestic	$ (13,321)	$ (3,822)
Foreign	(220)	(230)
Loss before taxes	$ (13,541)	$ (4,052)

The difference between the provision (benefit) for income taxes and the amount computed by applying the U.S. federal income tax rate for the year ended December 31, 2025 is as follows (in thousands):

	Years Ended December 31,	
	2025	
Income taxes (benefit) at statutory rates	$ (2,844)	21.0 %
State income tax (benefit), net of federal benefit [1]	75	(0.6)%
Foreign tax effects		
Australia		
Research credit	984	(7.3)%
Change in Valuation Allowance	(950)	7.0 %
Other	12	(0.1)%
Effect of changes in tax laws or rates enacted in the current period	—	— %
Tax credits		
Research and development credit	(732)	5.4 %
Changes in valuation allowance	(50)	0.4 %
Nontaxable or nondeductible items		
Permanent items	865	(6.4)%
Officers' compensation	475	(3.5)%
Stock compensation	1,761	(13.0)%
Changes in unrecognized tax benefits	71	(0.5)%
Other, net		
Expiration of attributes	229	(1.7)%
Other	104	(0.7)%
	$ —	0.00 %

[1] The states that contributed to the majority (greater than 50%) of the tax effect in this category include California and Massachusetts.

As previously disclosed, prior to the adoption of ASU 2023-09, the difference between the provision (benefit) for income taxes and the amount computed by applying the U.S. federal income tax rate for the year ended December 31, 2024 is as follows:

	2024
Federal income tax expense at statutory rate	21.00 %
State income tax, net of federal benefit	(3.75)%
State tax rate change	29.65 %
Permanent differences	(2.21)%
Research and development credit	43.95 %
Stock compensation	(5.49)%
Other	(12.88)%
Change in valuation allowance	(70.27)%
Effective income tax rate	— %

During 2025, the Company identified an immaterial error in the Company's deferred tax assets and corresponding valuation allowance as of December 31, 2024, relating to capitalized research and development costs which resulted in understated deferred tax assets and corresponding valuation allowance of approximately $0.9 million. For comparative purposes, the Company's 2024 tax disclosures herein have been revised to reflect the adjustment to the deferred tax assets and valuation allowance. The Company evaluated the error and concluded the impact was not material to its consolidated financial statements. The effect of the revision to the net deferred tax asset balance was zero, and the revision had no impact on the Company's consolidated balance sheet, consolidated statement of operations and comprehensive loss or consolidated statement of cash flows.

The major components of the Company's deferred tax assets as of December 31, 2025 and 2024 are shown below (in thousands).

	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 98,463	$ 85,686
Research and development credit carryforwards	12,357	12,767
Capitalized research and development costs	1,366	13,449
Stock compensation	674	3,570
Other	1,546	306
Total deferred tax assets	114,406	115,778
Valuation allowance	(113,743)	(115,532)
Deferred tax assets, net of valuation allowance	663	246
Deferred tax liabilities:		
Right-of-use assets	(654)	(246)
Other	(9)	—
Total deferred tax liabilities	(663)	(246)
Net deferred tax assets (liabilities)	$ —	$ —

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 $113.7 million and $115.5 million was established at December 31, 2025 and 2024, 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 valuation allowance decreased by approximately $1.8 million for the year ended December 31, 2025.

At December 31, 2025, the Company had federal, state and Australian net operating loss carryforwards of $369.4 million, $305.9 million, and $2.4 million, respectively, some of which will begin expiring in 2026 unless previously utilized. Included in the federal net operating loss carryforward is $195.8 of federal carryforward with no expiration date. The Australian losses may be carried forward indefinitely as well.

The Company also had federal and state research and development credit carryforwards of $13.3 million and $2.7 million, respectively. The federal research and development credit carryforwards will begin expiring in 2027, unless previously utilized. The state research credits begin to expire in 2027, unless previously utilized. Included in the state research credit carryforward is $0.6 million of carryforward with no expiration date. The Australian credits may be carried forward indefinitely as well.

Future utilization of the Company's net operating loss and research and development credit carryforwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code (IRC) Section 382 and 383, as a result of ownership changes that may have occurred or that could occur in the future. An ownership change occurs when a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. If a change in ownership were to have occurred or occurs in the future, the use of NOL and tax credits carryforwards may be limited or reduced. The Company does not expect this analysis to be completed within the next 12 months. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company accounts for income taxes in accordance with authoritative accounting guidance which states the impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

A reconciliation of the beginning and ending amount of uncertain tax benefits is as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Beginning balance uncertain tax benefits	$ 3,067	$ 2,761
Decreases related to prior year positions	—	(31)
Additions related to prior year positions	59	—
Additions related to current year positions	65	337
Decreases related to settlements with taxing authorities	—	—
Decreases as a result of a lapse of the applicable statute of limitations	—	—
Ending balance of unrecognized tax benefits	$ 3,191	$ 3,067

Included in the balance of uncertain tax benefits at December 31, 2025 and 2024 are $3.1 million and $2.9 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's policy is to record estimated interest and penalties related to uncertain tax benefits as income tax expense. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The tax years 2021 through 2024 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. There are currently no pending income tax examinations.

On July 4, 2025, the One Big Beautiful Bill Act (the "Act") was signed into law. The Act reinstates and makes permanent 100% first-year bonus depreciation under Section 168(k) for qualified property acquired and placed in service after January 19, 2025. Additionally, the Act allows current expensing of domestic research and experimental costs starting in 2025 and provides special retroactive relief for "smaller business taxpayers." The Company deducted the unamortized R&E expenditures as of December 31, 2024 on its 2024 tax return, resulting in no change in the Company's effective tax rate or cash tax liability due to the full valuation allowance. The Company has reflected the effects of the Act in its income tax provision in accordance with ASC 740 and there was no material impact.

9. STOCKHOLDERS' EQUITY

Equity Line

On October 21, 2024, the Company entered into a purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the purchase agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million of shares of the Company's common stock. Sales of such shares by the Company, if any, are subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 24-month period commencing on November 27, 2024, which is referred to as the "Commencement Date."

From time to time after the Commencement Date, at the Company's sole discretion, on any business day selected by the Company on which the closing sale price of the Company's common stock is not below $0.50 per share, the Company may direct Lincoln Park to purchase up to 30,000 shares of the Company's common stock (or up to 35,000 and 40,000 shares if the closing sale price of the Company's common stock on the day on which the Company initiates a purchase is not below $5.00 or $7.50, respectively, subject to customary adjustments for stock splits and similar transactions) at a purchase price equal to the lower of (i) the lowest sale price of the Company's common stock on the business day on which the Company initiates the purchase and (ii) the average of the three lowest closing sale prices of the Company's common stock during the 10-business day period immediately preceding the business day on which the Company initiates the purchase. However, Lincoln Park's maximum commitment in any single purchase may not exceed $500,000. In addition, the Company may also direct Lincoln Park to purchase other amounts of common stock as accelerated purchases and as additional accelerated purchases, subject to limits specified in the purchase agreement, at a purchase price per share calculated as specified in the purchase agreement, but in no case lower than the minimum price per share the Company stipulates in its notice to Lincoln Park initiating these purchases.

In addition, under applicable Nasdaq rules, the Company may not issue or sell to Lincoln Park under the purchase agreement more than 1,711,172 shares of the Company's common stock, which is referred to as the Exchange Cap, unless (i) the Company obtains stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of the Company's common stock to Lincoln Park under the purchase agreement equals or exceeds $3.59 per share (which represents the lower of (A) the official closing price per share of the Company's common stock on Nasdaq immediately preceding the signing of the purchase agreement and (B) the average official closing price of the Company's common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the purchase agreement). The Company may also not sell shares to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 4.99% of the Company's then outstanding shares of common stock, which limitation is referred to as the beneficial ownership cap. Lincoln Park, upon written notice to the Company, may increase the beneficial ownership cap to up to 9.99%. Any increase in the beneficial ownership cap will not be effective until the 61st day after such written notice is delivered to the Company.

In connection with entering into the purchase agreement, the Company issued 137,614 shares of its common stock to Lincoln Park in consideration for its commitment to purchase shares thereunder.

During the year ended December 31, 2025, the Company sold 1,470,000 shares of common stock under this agreement for gross proceeds of approximately $3.3 million, net of offering expenses of approximately $0.1 million.

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 agent. 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. In April 2024, the Company and Cantor mutually agreed to terminate the sales agreement with respect to Cantor. During the years ended December 31, 2025 and 2024, the Company sold 4,329,116 and 109,655 shares of common stock, respectively, under the sales agreement for aggregate gross proceeds of approximately $18.0 million and $0.5 million, respectively, net of offering expenses of approximately $0.4 million and $11,000, respectively.

Common Stock Warrants

The warrants outstanding as of December 31, 2025, are exercisable into 1,268,572 shares of common stock which had a fair value of $1.93 per share, based on the closing market price of the Company's common stock on December 31, 2025. The aggregate intrinsic value of warrants outstanding as of December 31, 2025, is calculated as

the difference between the exercise price of the warrants and the closing market price of the Company's common stock on that date. The intrinsic value of warrants outstanding as of December 31, 2025, was zero. The Company has performed an assessment of all warrants issued and determined that the Company's warrants are equity-classified.

Summary of Warrants Outstanding

A summary of warrants outstanding during the years ended December 31, 2025 and 2024 is presented below:

	Quantity of Warrants Outstanding as of			
Description	**December 31, 2025**	**December 31, 2024**	**Exercise Price**	**Expiration Date**
Initial Royalty Warrant [1]*	422,804	422,804	$ 4.10	12/22/2028
September 2023 Warrants [2]*	845,225	845,225	$ 9.11	3/1/2029
October 2016 Warrants [3]	542	542	$ 120.00	10/4/2026
Total Warrants Outstanding	1,268,571	1,268,571		

1) Refers to a warrant issued in connection with entering into the royalty interest financing agreement with UiE.

2) Refers to the warrants issued in connection with a registered direct offering the Company completed in September 2023.

3) Refers to a warrant issued in October 2016 to a former financial advisor.

* 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.

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 14,499,502 and 8,700,386 shares of common stock as of December 31, 2025 and 2024, respectively. There were no shares of preferred stock issued or outstanding as of December 31, 2025 or 2024.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2025:

Common stock reserved for issuance upon exercise of warrants outstanding	1,268,572
Common stock reserved for issuance upon exercise of options outstanding	1,409,042
Common stock reserved for future equity awards	540,043
Total	3,217,657

Reverse Stock Split

On July 1, 2024, the Company effected a 1-for-12 reverse split of its issued common stock. At the effective time of the reverse stock split, every 12 shares of the Company’s common stock was automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split reduced the number of issued and outstanding shares of the Company’s common stock from approximately 101.1 million to approximately 8.5 million. The reverse stock split did not change the number of authorized shares or the par value per share of the Company’s common stock.

10. STOCK-BASED COMPENSATION

2014 Employee Stock Purchase Plan

The Company’s 2014 Employee Stock Purchase Plan, or the ESPP, was suspended in June 2024. There was no stock-based compensation related to the ESPP for the years ended December 31, 2025 or December 31, 2024.

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. As a result of the approval of the 2022 Plan (as defined below) by the Company's stockholders in June 2022, no further awards have been or will be granted under the Amended 2014 Plan since such approval. 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 in June 2022, and became effective as of such approval. In April 2025, the Company's board of directors approved an amendment to the 2022 Plan to increase the number of shares of common stock available for issuance thereunder by 600,000, which was subsequently approved by the Company's stockholders on July 9, 2025. The 2022 Plan provides for the grant of stock-based incentive awards to employees, directors, consultants, and advisors.

As of December 31, 2025, the number of shares of common stock authorized for issuance under the 2022 Plan was 1,949,085, which is the sum of:

(a) 540,043 shares available for awards that may be granted under the 2022 Plan; plus

(b) 1,015,783 shares underlying awards granted under the 2022 Plan, plus

(c) 393,259 shares underlying awards granted under the Amended 2014 Plan, which if they expire, terminate or are otherwise forfeited will become available for issuance under the 2022 Plan.

Options granted are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. Stock options generally vest over a four-year term. The exercise price of each option is determined by the Company's board of directors or its compensation committee based on the estimated fair value of the Company's stock on the date of grant.

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, 2025 and 2024. The exercise price of all options granted during the years ended December 31, 2025 and 2024 was equal to the market value of the Company’s common stock on the date of grant. As of December 31, 2025, unamortized stock-based compensation expense of approximately $1.8 million will be amortized over the weighted average period of 1.2 years. The number of shares of common stock available for future awards granted under the 2022 Plan as of December 31, 2025 was 540,043.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value *
Outstanding at December 31, 2024	883,334	$ 14.58		
Granted	583,890	2.72		
Exercised	—	—		
Canceled/forfeited	(765)	3.18		
Expired	(57,417)	20.90		
Outstanding at December 31, 2025	1,409,042	$ 9.41	7.51	$ —
Options exercisable at December 31, 2025	870,141	$ 12.57	6.64	$ —
Options vested and expected to vest at December 31, 2025	870,141	$ 12.57	6.64	$ —

**The aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's common stock exceeded the exercise price of the stock options at December 31, 2025 for those stock options for which the quoted market price was in excess of the exercise price.*

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $2.02 and $4.10, respectively. The total fair value of stock options vested during the years ended December 31, 2025 and 2024, was approximately $1.5 million and $2.2 million, respectively.

Stock-Based Compensation Expense

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

	Years Ended December 31,	
	2025	2024
Research and development	$ 636,303	$ 833,689
Selling, general and administrative	860,259	1,369,567
Total	$ 1,496,562	$ 2,203,256

The weighted-average assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of their service on the Company's board of directors during the years ended December 31, 2025 and 2024 is as follows:

	2025	2024
Expected life in years	5.8	6.0
Risk-free interest rate	4.07 %	4.13 %
Expected volatility	86 %	90 %
Dividend yield	0.0 %	0.0 %

11. LEASED PROPERTIES

Finance Lease - Clean Room Space

On July 24, 2024, the Company entered into a scope of work (the "SOW") with an unrelated third party for a controlled clean room space in Massachusetts. The SOW became effective upon the execution of an associated License and Services Agreement (the "LSA"), which governs the SOW. On February 25, 2025, the parties entered into a termination agreement related to the original LSA and SOW and concurrently entered into a revised LSA and revised SOW, collectively, the Clean Room Agreement, primarily to clarify the location of the clean room subject to the arrangement. The term of the Clean Room Agreement is 22 months and commenced on March 1, 2025. Fixed payments are due at the beginning of each calendar quarter and variable amounts related to support services are due monthly based on services provided during the preceding month. Upon execution of the SOW, the Company made a prepayment of approximately $459,000. The Clean Room Agreement may be renewed each year and if renewed, the fixed payment amount may increase yearly by up to 5%.

The Company determined that the Clean Room Agreement is a finance lease. On the commencement date, the Company recorded an initial finance lease ROU asset and related lease liability of approximately $3.3 million and $2.8 million, respectively. Included in the $3.3 million finance ROU asset is the $459,000 prepayment which was reclassified to the finance lease ROU asset on the commencement date. The lease does not provide an implicit rate and therefore the Company used its incremental borrowing rate as the discount rate when measuring the finance lease liability. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company used an incremental borrowing rate consisting of the current prime rate plus 200 basis points for its finance lease. During 2025, the parties executed two change orders primarily to amend the total contract consideration under the lease arrangement. The Company evaluated these amendments and concluded they represented a lease modification. As such, the finance lease ROU asset and finance lease liability were remeasured using an incremental borrowing rate at the date of the modification resulting in a decrease of approximately $83,000 to both the ROU asset and corresponding finance lease liability.

Operating Leases - General Office Space

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced in July 2018 and, as a result of an extension entered into in March 2024, expires on October 31, 2027. The extension entered into in March 2024 resulted in additional operating lease liabilities and ROU assets of approximately $0.4 million in March 2024.

MBI, a wholly-owned subsidiary the Company, leases general office and laboratory space in Massachusetts. The lease commenced on November 1, 2023 for a term of three years, expiring on December 31, 2026. On

December 18, 2025, the term of the lease was extended to December 31, 2027, which resulted in additional operating lease liabilities and ROU assets of approximately $0.4 million.

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.

Aggregate Lease Information

The components of lease cost recorded in the Company's consolidated statements of operations and comprehensive loss were as follows:

	December 31,	
	2025	2024
Operating lease cost	$ 828,036	$ 766,257
Finance lease cost		
Amortization of finance lease	1,472,366	—
Interest on finance lease liability	152,475	—
Variable lease cost	124,205	172,337
Total lease cost	$ 2,577,082	$ 938,594

Maturities of the Company's finance and operating lease liabilities as of December 31, 2025 were as follows:

Year	Operating Leases	Finance Lease	Total
2026	$ 680,081	$ 1,529,500	$ 2,209,581
2027	583,046	—	583,046
Total lease payments	1,263,127	1,529,500	2,792,627
Less: amount representing interest	(101,210)	(35,398)	(136,608)
Present value of lease liabilities	$ 1,161,917	$ 1,494,102	$ 2,656,019

The weighted-average remaining lease terms and discount rates related to the Company's leases were as follows:

	December 31,	
	2025	2024
Weighted-average remaining lease term (in years)		
Operating leases	1.92	2.42
Finance lease	1.00	—
Weighted-average discount rate		
Operating leases	9.1 %	10.5 %
Finance lease	9.5 %	—

Supplemental cash flow information related to the Company's leases was as follows:

	December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities		
Financing cash flows from finance lease	$ 1,264,188	$ —
Operating cash flows from finance lease	$ 152,475	$ —
Operating cash flows from operating leases	$ 659,626	$ 615,325

12. ROYALTY INTEREST FINANCING

In December 2023, the Company entered into a royalty interest financing agreement, or the Royalty Interest Agreement, with United in Endeavour, LLC, or UiE, under which UiE acquired a portion of the Company's royalty interest in XACIATO. The Company received $5.0 million from UiE when the parties entered into the Royalty Interest Agreement (the "Initial Investment"), and until December 31, 2026, the Company may, in its sole discretion, but subject to XOMA's prior written consent (see Note 13, Royalty Purchase Agreements), elect to receive three additional payments (each a "Supplemental Investment") from UiE of up to an aggregate of $7.0 million, for a total of up to $12.0 million.

Under the Royalty Interest Agreement, the Company agreed to make the following payments to UiE, until such time when UiE has received aggregate payments equaling a 12% internal rate of return (the “IRR”) on the Initial Investment and each Supplemental Investment, if any: (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 UiE to the extent UiE has not received payments equaling the IRR by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if UiE has not received payments equaling the IRR 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 UiE quarterly payments evenly divided over a two-year term ("Catch-up Payments"), such that UiE will have obtained the IRR, taking into account all other payments received by UiE from the Company under the Royalty Interest Agreement. UiE’s right to receive payments will terminate when UiE has received payments in an amount equal to the IRR (such period of time is referred to as the "Financing Term"). Under the Royalty Interest Agreement, the Company has the right, at any time and from time to time, to make voluntary prepayments to UiE, and such payments will be credited against the IRR. In addition, the Company has the right at any time to pay in full and retire all of the Company's payment obligations to UiE by paying the full amount of the IRR (the "Call Payment"), calculated as of the date of the payment.

The Company evaluated the terms of the Royalty Interest Agreement and concluded that its features 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, which will be amortized under the effective interest method over the estimated Financing Term. 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 Financing Term. In addition, in accordance with ASC 470, Debt, any royalties and milestone payments received by or on behalf of the Company from Organon from and after the date of the Initial Investment are recorded as non-cash royalty revenue in the consolidated statements of operations as a reduction to the liability related to the sale of future royalties.

To determine the amortization of the liability related to the sale of future royalties, the Company is required to estimate the duration of the Financing Term and the total amount of future payments to UiE during the Financing Term. These estimates involve significant estimates and assumptions regarding future Net Royalty Payments that impact both the amount of the liability related to the sale of future royalties and the interest expense that will be recognized over the Financing Term. The Company will periodically reassess the estimated amounts due and payable to UiE and the duration of the Financing Term and to the extent the estimated amount or timing of such payments is materially different than the prior estimate, an adjustment will be recorded in future periods, 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 UiE, and correspondingly, the amount of interest expense and interest payable 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 XACIATO and its components; perceived superiority of XACIATO's cure rates compared to other available treatments; patient satisfaction and willingness to use XACIATO 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 the length of the Financing Term and the total amount owed to UiE. During the year ended December 31, 2025, based on Net Royalty Payments to date and other factors, the Company updated its forecast of Net Royalty Payments, resulting in an estimated Financing Term that is approximately 9.5 years longer than previously estimated, extending through 2037, and as of December 31, 2025, the effective interest rate on the liability related to the sale of future royalties is 12.8%. Under the current estimated Financing Term, the estimated total amount potentially owed to UiE would be approximately $22.0 million, substantially all of which would be paid as Catch-up Payments. However, as discussed above, the Company has the right to make voluntary prepayments to UiE that would be credited against the IRR, as well as the right to make the Call Payment, either of which actions could reduce the total amount owed to UiE, potentially materially.

Warrants

In connection with entering into the Royalty Interest Agreement, the Company issued to UiE a warrant (the "Initial Royalty Warrant") to purchase up to 422,804 shares of the Company's common stock (see Note 9, Stockholders' Equity). In addition, for every $1.0 million of Supplemental Investment, the Company will issue to UiE a warrant to purchase 84,561 shares of common stock. If the Company elects to receive the maximum amount of Supplement Investments, the Company would issue to UiE warrants to purchase an aggregate of up to 591,927 shares of common stock (collectively the "Additional Royalty Warrants," and together with the Initial Royalty Warrant, the "Royalty Interest Agreement Warrants"). As of December 31, 2025, the Company has only issued the Initial Royalty Warrant.

The Initial Royalty Warrant was deemed to be an equity classified warrant and recorded under additional paid in capital. The fair value of the Initial Royalty Warrant was determined to be $0.8 million (Note 9) and was recorded as a debt discount against the Initial Investment.

The following table shows the activity of the liability related to the sale of future royalties since the date of the Initial Investment through the period indicated:

	December 31,	
	2025	2024
Upfront payment from the sale of future royalties	$ 5,000,000	$ 5,000,000
Debt issuance cost	(276,101)	(276,101)
Relative fair value of Initial Royalty Warrant	(834,512)	(834,512)
Royalty payments	(8,284)	(2,189)
Non-cash interest expense and interest payable associated with the sale of future royalties	1,517,485	862,626
Liability related to the sale of future royalties	$ 5,398,588	$ 4,749,824

13. ROYALTY PURCHASE AGREEMENTS

In April 2024, the Company entered into a traditional royalty purchase agreement (the "XACIATO RPA"), and a synthetic royalty purchase agreement (the "Synthetic RPA and together with the XACIATO RPA, the "Royalty Purchase Agreements") with XOMA pursuant to which XOMA paid $22.0 million to the Company. In addition, if XOMA receives total payments under the Royalty Purchase Agreements (as described below) equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to the Company for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements (such $11.0 million payments to the Company, the "Contingent Purchase Price Payments").

Under the Royalty Purchase Agreements, the Company sold, assigned, transferred and conveyed its right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments the Company would otherwise have the right to receive from and after April 1, 2024 under the Company's exclusive license agreement with Organon, based on net sales of XACIATO, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of the Company under its exclusive license agreement with third-party licensors TriLogic and MilanaPharm, and (ii) all payments due and payable and actually paid by or on behalf of the Company under the Royalty Interest Agreement between the Company and UiE (such net amount, the “Purchased Receivables”);

(b) 25% of the $20.0 million payment that the Company could have potentially received under the Company's since terminated license agreement with Bayer relating to Ovaprene; and

(c) a synthetic royalty of 4.0% of the Company's, its affiliates’ and its sublicensees’ future net sales of Ovaprene, and 2.0% of the Company's, its affiliates’ and its sublicensees’ future net sales of Sildenafil Cream and DARE to PLAY™ Sildenafil Cream; *provided, however*, that, if XOMA receives total payments under the Royalty Purchase Agreements, net of any Contingent Purchase Price Payments made to the Company, equal to an amount that exceeds $110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (we refer to the amounts described in this clause (c) as the “Revenue Participation Right”).

Pursuant to the XACIATO RPA, XOMA, at its sole cost and discretion, may repay in full and retire all of the Company's payment obligations to UiE under the Royalty Interest Agreement. If XOMA does so, no further amounts in respect of the Royalty Interest Agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the XACIATO RPA. The Company cannot elect to receive any additional funding from UiE under the Royalty Interest Agreement without XOMA’s prior written consent. In connection with the synthetic royalty purchase agreement, the Company granted to XOMA a security interest in certain product assets related to Ovaprene, Sildenafil Cream and DARE to PLAY.

The $22.0 million the Company received from XOMA, less transaction costs of approximately $1.6 million, was allocated to the XACIATO RPA and recorded as other income on the Company's consolidated statement of operations and comprehensive loss in the second quarter of 2024. See Note 2, Basis of Presentation and Summary of Significant Accounting Policies, for additional information.

14. COMMITMENTS AND CONTINGENCIES

Insurance Financing

In each of July 2025 and 2024, the Company obtained financing for certain director and officer and other insurance premiums. The total premiums, taxes and fees financed each year was approximately $0.5 million and $0.6 million, respectively, 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 unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreements and the Company assigned to the lender a first priority lien on and a security interest in the financed insurance policies. With respect to the financing obtained in July 2025, the Company will make monthly installment payments through March 20, 2026. With respect to the financing obtained in July 2024, the Company made monthly installment payments through April 20, 2025. 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, 2025, the Company's remaining obligation for the financing obtained in July 2025 was approximately $0.2 million, and the Company had no remaining obligation for the financing obtained in July 2024. As of December 31, 2024, the Company's remaining obligation for the financing obtained in July 2024 was approximately $0.2 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 is being conducted within NICHD’s Contraceptive Clinical Trials 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 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. The Company has paid $5.5 million to NICHD, $0.5 million of which was paid in July 2024 and

$5.0 million of which was paid in prior years. The Company had no remaining payment obligation under the CRADA at December 31, 2025.

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 employees 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 six or twelve months of base salary and to receive continuing health benefits coverage for periods equal to either six 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 nine or eighteen months of base salary and target bonus and to receive continuing health benefits coverage for periods ranging between nine 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.

Related-Party Agreement

In January 2024, the Company entered into a consulting agreement with its former Chief Financial Officer 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 paid its former Chief Financial Officer $31,667 per month and reimbursed her up to $500 per month for her health insurance premiums.

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 each participant's cash compensation. The Company made matching contributions of approximately $0.2 million during each of the years ended December 31, 2025 and 2024.

15. GRANT AWARDS

October 2024 Grant Award

In October 2024, the Company entered into a subaward agreement with National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell (the "CMF") under which the Company is entitled to receive funding of up to $10.0 million in milestone-based payments subject to the Company's achievement over an approximately 24-month period of specified research activities and objectives relating to the advancement of the Company's DARE-HPV development program, including commencement of a Phase 2 clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for the clearance of high-risk HPV infection in women. The subaward agreement was the result of the Company's selection by Advanced Research Projects Agency for Health (ARPA-H), part of the U.S. Department of Health and Human Services. The CMF is a consortium management firm that received funding from the federal agency for the subaward agreement.

The Company receives funding in advance and tracks and reports eligible expenses incurred to the federal agency. The Company is required to apply the funds it receives solely toward direct costs for the funded project, other than an approximately 22% indirect cost allowance. An "indirect cost allowance" refers to the portion of the grant funds the Company receives that it may apply toward general overhead and administrative expenses that support the entire operations of the Company and which may be applied as the direct costs for the funded project are incurred. Funds received that have not been spent are recorded both in cash and cash equivalents and in deferred grant funding

liability in the Company's consolidated balance sheets. Funds that have been spent but not yet expensed in accordance with GAAP or not spent on direct costs for the funded project in excess of the indirect cost allowance are also recorded in deferred grant funding liability.

Through December 31, 2025, the Company had received payments totaling $5.5 million under this award. The Company recorded credits to research and development expense of approximately $3.1 million and $0.4 million for costs related to this award for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, the Company recorded approximately $2.0 million and $0.6 million in deferred grant funding liability related to this award in the Company's consolidated balance sheets, respectively.

See Note 17, Subsequent Events, for information regarding a payment received in February 2026 under this award.

NICHD and NIH Non-Dilutive Grant Funding

The Company has received notices of awards and grant funding from NICHD and the National Institutes of Health, or NIH, to support the development of several of its product candidates. NICHD and the NIH issue 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. The federal agency that administers funding to the NIH is the Small Business Innovation Research (SBIR). In October 2025, legislative authority for the SBIR program expired and, to date, it has not been reauthorized by Congress. In November 2025, NIH announced that it will not issue continuation awards for existing projects until the SBIR program is reauthorized. As a result of this funding freeze, the Company currently does not anticipate receiving additional funding under this award until and unless the SBIR program is reauthorized by Congress.

DARE-HPV

In December 2024, the Company received a notice of award from the National Institute of Allergy and Infectious Diseases (NIAID), a component of the NIH, that the Company was awarded a $1.0 million grant in support of non-clinical activities for the development of DARE-HPV for an initial project year of December 2024 through November 2025, and that an additional $1.0 million was recommended for the subsequent project year, subject to the availability of funds and satisfactory progress of the project, as determined by NIAID. The Company recorded $0.7 million and $0 credits to research and development expense for costs related to the NIH award for the years ended December 31, 2025 and 2024, respectively. The Company recorded a receivable of approximately $11,000 at December 31, 2025 for expenses incurred through such date that it believes are eligible for reimbursement under this award.

DARE-PTB1

In December 2023, the Company received a notice of award from NICHD of approximately $2.0 million to support the development of DARE-PTB1. The award is to be used to support what is referred to as the "Phase II" segment of the project outlined in the Company's grant application through November 2026. The Company recorded credits to research and development expense for costs related to this award of approximately $0.7 million and $0.7 million for the years ended December 31, 2025 and 2024, respectively. The Company recorded a receivable of $0 and approximately $84,000 at December 31, 2025 and 2024, respectively, for expenses incurred through such date that it believes are eligible for reimbursement under this award.

DARE-PTB2

In July 2023, the Company received a notice of award from NICHD of approximately $0.4 million to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds supported activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida.

The Company received aggregate reimbursements under this award of approximately $0.4 million during the grant period, which ended in July 2024. No further funds are available under this award.

Other Non-Dilutive Grant Funding

As described below, the Company has received substantial funding under grant agreements it entered into with the Gates Foundation, or the Foundation. The Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. The Company is required to apply the funds it receives solely toward direct costs for the funded projects, other than an approximately 5%-15% indirect cost allowance (see "October 2024 Grant Awards" for more information regarding the indirect cost allowance). Funds received that have not been spent are recorded both in cash and cash equivalents and in deferred grant funding liability in the Company's consolidated balance sheets. Funds spent but not yet expensed in accordance with GAAP or not spent on direct costs for the funded project in excess of the indirect cost allowance are also recorded in deferred grant funding liability.

The grant agreements include the Foundation's standard discretionary termination provisions. Any grant funds received that have not been committed to the funded project or spent in compliance with the applicable grant agreement must be returned promptly to the Foundation upon expiration or termination of the agreement.

2024 Contraceptive Product Candidate Grant Agreement

In November 2024, the Company entered into a grant agreement with the Foundation under which the Company was awarded a grant of up to approximately $10.7 million to support (i) expansion of the number of study sites in the ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in low- and middle-income country settings who need or would prefer to use such a product to avoid an unplanned pregnancy. The term of the agreement, as amended, extends through March 2027. An initial payment of approximately $5.4 million was made to the Company in November 2024 and a second payment of approximately $3.6 million was made to the Company in November 2025. Additional payments are contingent upon the Company's achievement of specified development and reporting milestones during the term of the grant agreement. The Company will track and report eligible expenses incurred to the Foundation.

The Company recorded credits to research and development expense of approximately $3.7 million and $0.2 million for costs related to this award for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, the Company recorded approximately $5.1 million and $5.2 million of deferred grant funding liability related to this award in the Company's consolidated balance sheets, respectively.

2024 Biotherapeutic Product Grant Agreement

In January 2024, the Company entered into an agreement with the Foundation under which the Company was awarded $750,000 to fund activities related to bacteria-based live biotherapeutic product development. The Company received the full amount of the award in January 2024. The Company recorded credits to research and development expense of approximately $0.7 million for costs related to this award for the year ended December 31, 2024. The grant period ended in November 2024. No further funds are available under this award.

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 term of the agreement, as amended, extends through December 2027. The agreement supports technology development and preclinical activities 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, 2025, the Company had received a cumulative total of approximately $41.8 million in funding under the agreement. 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 $8.2 million and $6.2 million for costs related to this award for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, the Company recorded approximately $12.6 million and $10.8 million of deferred grant funding liability related to this award in the Company's consolidated balance sheets, respectively.

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. The Company received the full amount of the award in November 2022. The Company recorded credits to

research and development expense of approximately $0.2 million for costs related to this award for the year ended December 31, 2024. The Company had no remaining deferred grant funding liability related to this award as of December 31, 2024.

16. SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker (“CODM”), in deciding how to allocate resources and in assessing performance. The Company and the Company’s chief operating decision maker view the Company’s operations and manage its business in one operating segment, which is the business of identifying, developing and commercializing pharmaceutical products that target unmet needs in women's health. The CODM, who is the chief executive officer (“CEO”), manages and allocates resources to the operations of the Company on a consolidated basis. The Company’s measure of segment profit or loss is net loss. Managing and allocating resources on a consolidated basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with the Company’s long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The CODM does not review assets in evaluating the results of the Company, and therefore, such information is not presented. In addition, substantially all of the Company's revenue was generated in the United States and substantially all of the Company's long-lived assets reside in the United States.

The following table summarizes the segment's financial information including the Company’s significant segment expenses:

	Year Ended December 31,	
	2025	2024
Revenue:		
License fee and other revenues	$ 1,030,193	$ 9,784
Total revenue	1,030,193	9,784
Cost of revenues	295,799	—
Segment operating expenses:		
Research and development:		
Direct program costs:		
Ovaprene [1]	5,016,187	8,518,495
Sildenafil Cream, 3.6% [2]	1,143,221	2,361,052
Other advanced clinical stage programs	2,805,127	1,421,888
Phase 1 and Phase 1-ready clinical stage programs [1]	1,548,800	761,721
Preclinical stage programs [1]	6,365,438	4,233,762
Other development programs	—	27,542
Contra-R&D expenses [3]	(13,919,881)	(7,685,533)
Total research and development direct program costs	2,958,892	9,638,927
Indirect costs:		
Personnel-related (including stock compensation)	4,691,957	5,611,057
Other indirect costs	281,787	254,772
Contra R&D expenses	(2,409,284)	(1,199,548)
Total research and development indirect costs	2,564,460	4,666,281
Selling, general and administrative	8,763,376	9,156,061
Total segment operating expenses	14,286,728	23,461,269
Loss from operations	(13,552,334)	(23,451,485)
Sale of royalty and milestone rights, net	—	20,379,376
Interest expense	822,709	857,364
Interest income	(679,740)	(539,743)
Other income (expense), net	(296,029)	663,869
Net loss	$ (13,399,274)	$ (4,053,599)

(1) The applicable program(s) receive grant funding and/or the Tax Incentive. The amount of R&D expense for the period indicated is shown on a gross basis (i.e., without deducting the amount of contra R&D expense for the applicable program(s). See footnote (3) below.

(2) For 2025, the dollar amount also includes expenses for DARE to PLAY.

(3) These contra R&D expenses were recognized as follows for the years ended December 31, 2025 and 2024: (a) Ovaprene, $2.5 million, and $0.2 million, respectively; (b) Other advanced clinical stage programs, $2.9 million and $0, respectively, (c) Phase 1 and Phase 1-ready clinical stage programs, $0.4 million and $1.3 million, respectively; and (d) Preclinical stage programs, $8.1 million and $6.2 million, respectively.

17. SUBSEQUENT EVENTS

Receipt of Payment Under October 2024 Grant Award

On February 19, 2026, the Company received a $2.0 million payment from CMF under the agreement the Company entered into with CMF in October 2024 to support the development of DARE-HPV. For a discussion of this agreement, see Note 15, Grant Awards. Taking into account this payment, the Company has received a cumulative total of approximately $7.5 million of the up to $10.0 million in potential funding under this award.

Designation of Series A Preferred Stock

On January 23, 2026, in anticipation of the initial closing of its Regulation A offering (see "—Regulation A Offering," below), the Company filed a Certificate of Designation of Series A Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Delaware, which became effective upon filing.

The Certificate of Designation designates 4,999,620 shares of the Company's authorized preferred stock, $0.01 par value per share, as Series A Convertible Preferred Stock (the "Series A Preferred Stock") and establishes the following powers, preferences and rights, and qualifications, limitations and restrictions of such series of preferred stock:

Voting Rights. Except as required by law, the Series A Preferred Stock has no voting rights.

Ranking. The Series A Preferred Stock ranks, as to rights upon liquidation, dissolution, or winding up, senior to the Company's common stock. The terms of the Series A Preferred Stock do not limit the Company's ability to (i) incur indebtedness or (ii) issue additional equity securities that are senior in rank to the Series A Preferred Stock as to dividend or distribution rights and rights upon liquidation, dissolution or winding up.

Stated Value. Each share of the Series A Preferred Stock has an initial stated value of $5.00, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events affecting the Series A Preferred Stock.

Dividend Rights. Holders of the Series A Preferred Stock are not entitled to receive any dividends.

Liquidation Preference. The liquidation preference for each share of the Series A Preferred Stock is $5.00 per share, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events affecting the Series A Preferred Stock. Upon the Company's liquidation, dissolution or winding up, to the extent the Company has the cash available, holders of shares of the Series A Preferred Stock will be entitled to receive the liquidation preference with respect to their shares of Series A Preferred Stock.

Company Call Option. Commencing on the third anniversary of the initial closing of the Regulation A offering and continuing indefinitely thereafter, the Company will have a right to call for redemption the outstanding shares of the Series A Preferred Stock at a per share call price equal to the lesser of (i) the stated value per share plus a non-compounded rate of return calculated at 8% per annum, and (ii) 200% of the stated value per share, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events affecting the Series A Preferred Stock.

Conversion at Option of Holder. At any time after issuance, each share of the Series A Preferred Stock is convertible at the option of the holder thereof into shares of the Company's common stock at a conversion price of $2.50 per share (the "Initial Conversion Price"), subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events. Accordingly, each share of the Series A Preferred Stock is initially convertible into two shares of the Company's common stock.

Forced Conversion. If at any time after issuance, any of the following events occurs, the Company will have the right to require the holders of shares of Series A Preferred Stock to convert all, or any portion of, their shares of Series A Preferred Stock into shares of the Company's common stock: (a) a change in control, (b) if the closing price of the Company's common stock is at or above $4.50 per share, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events, for any 10 trading days out of any 30 consecutive trading day period, or (c) if the Company consummates a firm commitment public offering of shares of the Company's common stock resulting in gross proceeds of at least $15.0 million at an offering price per share equal to or greater than $4.50, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events.

Limitations on Conversion. Notwithstanding the conversion rights described above, to the extent prohibited by applicable rules of The Nasdaq Stock Market LLC or any other national securities exchange or trading market on which the Company's capital stock is listed, the Company will not issue shares of Common Stock upon conversion of shares of Series A Preferred Stock if such issuance will result in a change of control of the Company under Nasdaq Listing Rule 5635(b) or would violate Nasdaq Listing Rule 5635(d), in each case, unless the Company obtains stockholder approval of such issuance in accordance with such applicable rules. As it applies to the Regulation A offering, Nasdaq Listing Rule 5635(d) generally provides that if the initial conversion price of the Series A Preferred Stock is less than the "Minimum Price" (as such term is defined in Nasdaq Listing Rule 5635(d)) plus $0.125 (with such amount added to account for the valuation, under the Nasdaq Listing Rules, of the warrants issued as part of the units in the Offering), stockholder approval is required prior to the issuance of shares of the Company's common stock in the offering that equals or exceeds 20% or more of the total number of shares of the Company's common stock outstanding as of immediately prior the initial closing the offering. For additional information regarding the applicability of Nasdaq Listing Rule 5635(d), see "Regulation A Offering—Initial Closing," below.

No Redemption Right. The Series A Preferred Stock has no maturity date, and the Company is not required to redeem any of the Series A Preferred Stock at any time.

Regulation A Offering

On January 27, 2026, the Company completed the initial closing of its Regulation A offering of up to 4,854,000 units (each, an "Investor Unit" and collectively the "Investor Units"), each consisting of one share of Series A Preferred Stock and two warrants, each to purchase one share of the Company's common stock ("Investor Warrants"), with each Investor Unit being offered at an offering price of $5.00 (the "Regulation A offering"). The closing price of the Company's common stock on January 26, 2026, was $1.90, and because the Initial Conversion Price exceeded the sum of that closing price plus $0.125, the limitations under Nasdaq Listing Rule 5635(d) that could have applied to the conversion of the Series A Preferred Stock and to the exercise of the Investor Warrants issued in the Regulation A offering will not apply to any of the shares of Series A Preferred Stock or the Investor Warrants that are part of the up to 4,854,000 Investors Units that may be issued in the Regulation A offering.

The Regulation A offering is being conducted pursuant to the Company's offering statement on Form 1-A (File No. 024-12688), as amended (the "Offering Statement"), which was qualified by the SEC on January 5, 2026, and the offering circular, dated January 6, 2026, which forms a part thereof (the "Offering Circular"). The Regulation A offering is being conducted on a "best efforts" basis pursuant to a selling agency agreement, dated January 5, 2026 (the "Selling Agency Agreement"), between the Company and Digital Offering, LLC ("Digital Offering"), acting as the lead selling agent for the Regulation A offering. Digital Offering is not required to sell any specific number or dollar amount of Investor Units. The Company will pay to Digital Offering a placement fee equal to 7.25% of the offering price per Investor Unit sold in the Regulation A offering. The Company will also issue Agent Unit Warrants (as defined below) to purchase that number of Agent Units (as defined below) equal to 3% of the total number of Investor Units sold in the Regulation A offering. In addition, the Company paid Digital Offering a $25,000 consulting fee and reimbursed or will reimburse Digital Offering for up to $85,000 of its reasonable, out-of-pocket, and documented fees and expenses incurred in connection with the Regulation A offering.

The Investor Warrants are exercisable at any time after issuance through the 36-month anniversary of their date of issuance at an exercise price of $4.00 per share of the Company's common stock, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events. Notwithstanding the foregoing, there are certain limitations on the exercise of the Investor Warrants to the extent a holder (together with its affiliates) would own more than 4.99% (or 9.99%) of the outstanding the Company's common stock immediately after exercise.

The Regulation A offering will terminate at the earliest of (i) the date on which the maximum offering amount of Investor Units has been sold, (ii) January 5, 2027 (one year after the date on which the Offering Statement was qualified by the SEC) and (iii) the date on which the Company determines to terminate the Regulation A offering, which the Company may do in its sole discretion at any time and for any reason or no reason.

The Offering Circular also relates to (i) 145,620 warrants (the "Agent Unit Warrants") to purchase up to 145,620 units (the "Agent Units") issuable to the selling agent(s) for the Regulation A offering, each Agent Unit consisting of one share of Series A Preferred Stock and two warrants, each to purchase one share of the Company's common stock, (ii) up to 145,620 shares of Series A Preferred Stock issuable upon exercise of the Agent Unit Warrants and up to 291,240 shares of the Company's common stock issuable upon conversion of such shares of Series A Preferred Stock, and (iii) up to 291,240 warrants (the "Agent Common Warrants") issuable upon exercise of the Agent Unit Warrants and up to 291,240 shares of the Company's common stock issuable upon exercise of the Agent Common Warrants. The Company will issue Agent Unit Warrants to purchase that number of Agent Units equal to 3% of the total number of Investor Units sold in the Regulation A offering.

The exercise price per Agent Unit Warrant is $6.25, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events. The Agent Unit Warrants will expire on January 7, 2031, which is the five-year anniversary of the date of commencement of sales in the Regulation A offering.

The exercise price per Agent Common Warrant is $4.00 per share, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events. The terms of the Agent Common Warrant are substantially similar to the terms of the Investor Warrant, except that they expire on January 7, 2031.

As of the filing date of this report, the Company has issued an aggregate of 65,640 Investor Units consisting of 65,640 shares of Series A Preferred Stock and Investor Warrants to purchase up to 131,280 shares of the Company's common stock, for gross proceeds of approximately $328,200, and 1,968 Agent Units.

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

As of March 26, 2026, Daré Bioscience, Inc. (the "Company," "we," "our" and "us") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act"): common stock, $0.0001 par value per share ("common stock").

General

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

Authorized Capital

We are authorized to issue up to 240,000,000 shares of common stock and up to 5,000,000 shares of preferred stock, $0.01 par value per share (the "preferred stock").

Preferred Stock

On January 23, 2026, we filed a Certificate of Designation of Series A Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Delaware, which became effective upon filing. The Certificate of Designation designates 4,999,620 shares of our authorized preferred stock as Series A Convertible Preferred Stock ("Series A Preferred Stock"), which our board of directors has the right to issue without further action by our stockholders. As of March 26, 2026, 65,640 shares of our Series A Preferred Stock were outstanding. Our Series A Preferred Stock ranks, as to rights upon our liquidation, dissolution, or winding up, senior to our common stock. The liquidation preference for each share of our Series A Preferred Stock is $5.00 per share, subject to customary adjustments in the event of stock dividends, stock splits, reorganizations or similar events affecting our Series A Preferred Stock. Except as required by law, the Series A Preferred Stock has no voting rights. For additional information regarding the powers, preferences and rights, and qualifications, limitations and restrictions of our Series A Preferred Stock, see Note 17, "Subsequent Events," to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Assuming no change in the authorized number of shares of Series A Preferred Stock, our board of directors has the authority, without further action by our stockholders, to issue up to 380 additional shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the holders of our common stock. In addition, to the extent that any shares of Series A Preferred Stock previously designated under the Certificate of Designation are not issued, our board of directors may, subject to applicable law, redesignate such shares as a new or different series of preferred stock and establish the rights, preferences, privileges and restrictions of such series, any or all of which may be greater than the rights of the holders of our common stock.

Rights of Holders of our Common Stock

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Bylaw Amendments. Our board of directors, by majority vote, may amend, alter or repeal our Bylaws and may adopt new Bylaws. Our stockholders may not adopt, amend, alter or repeal our Bylaws

or adopt any provision inconsistent therewith, unless such action is approved, in addition to any vote required by our Certificate, by the affirmative vote of holders of at least 75% of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors, and the affirmative vote of holders of at least 75% of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors is required to amend or repeal, or to adopt any provision inconsistent with, the foregoing. These provisions may inhibit the ability of an acquirer from amending our Certificate or our Bylaws to facilitate a hostile acquisition and may allow our board of directors to take additional actions to prevent a hostile acquisition.

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

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

In addition, we are subject to Section 203 of the DGCL, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any “business combination” with any “interested stockholder” for three years following the date that such stockholder became an interested stockholder, unless: (i) before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (a) by persons who are directors and also officers and (b) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock not owned by the interested stockholder.

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

Exclusive Forum

Our Bylaws provides that, unless we consent in writing to the selection of an alternative forum: (1) the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of the Company; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of the Company, to the Company or its stockholders; (iii) any action or proceeding asserting a claim against the Company or any current or former director, officer or other employee of the Company, arising out of or pursuant to any provision of the DGCL, the Certificate of Incorporation or our Bylaws (as each may be amended from time to time); (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or our Bylaws (including any right, obligation, or remedy thereunder); (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a

claim against the Company or any director, officer or other employee of the Company, governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; and (2) 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 of 1933, as amended.

Our Bylaws also provide that if any action the subject matter of which is within the scope of clause (1) of the paragraph above is filed in a court other than a court located within the State of Delaware (a "Foreign Action") in the name of any stockholder, such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce clause (1) of the paragraph above (an "Enforcement Action") and (ii) having service of process made upon such stockholder in any such Enforcement Action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

Our Bylaws also provide that any person or entity purchasing or otherwise acquiring or holding any interest in any security of the Company shall be deemed to have notice of and consented to the provisions of the foregoing.

Dissenters' Rights of Appraisal and Payment

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

Exhibit 10.10

CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

GRANT AGREEMENT

Investment ID INV-026060

AGREEMENT SUMMARY & SIGNATURE PAGE

GRANTEE INFORMATION	
Name:	Dare Bioscience, Inc.
Tax Status:	Not exempt from federal income tax under U.S. IRC § 501(c)(3) You confirm that the above information is correct and agree to notify the Foundation immediately of any change.
Expenditure Responsibility:	This Agreement is subject to "expenditure responsibility" requirements under the U.S. Internal Revenue Code.
Mailing Address:	3655 Nobel Drive Suite 260, San Diego, California 92122, USA
Primary Contact:	Nicolas Pacelli, Vice President, Business Development, [***]

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, Washington 98102, USA
Primary Contact:	Kirsten Vogelsong, Senior Program Officer, Contraceptive Development, Integrated Development, [***]

AGREEMENT INFORMATION	
Title:	Personal Contraceptive System (DARE LARC1)
"Charitable Purpose":	To advance the development of a novel long-acting, user-controlled hormonal contraceptive implant suitable for use by women in low-resource settings
"Start Date":	Date of last signature
"End Date":	November 1, 2026
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Investment Document (date submitted [***]) • Results Framework and Tracker (date submitted [***]) • Budget (date submitted [***])

THIS AGREEMENT is between Dare Bioscience, Inc. ("Dare Bioscience", "You" or "Grantee") and the Bill & Melinda Gates Foundation ("Foundation"), and is effective as of date of last signature. Each party to this Agreement may be referred to individually as a "Party" and together as the "Parties." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

/s/ Kirsten Vogelsong

By: Kirsten Vogelsong

Title: Senior Program Officer

June 24, 2021

Date

DARE BIOSCIENCE, INC.

/s/ Sabrina Johnson

By: Sabrina Johnson

Title: CEO

June 30, 2021

Date

GRANT AGREEMENT
Investment ID INV-026060

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT
The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE
Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING
You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

ACCOUNTING FOR PERSONNEL TIME
You will track the time of all employees, contingent workers, and any other individuals whose compensation will be paid in whole or in part by Grant Funds. Such individuals will keep records (e.g., timesheets) of actual time worked on the Project in increments of sixty minutes or less and brief descriptions of tasks performed. You will report actual time worked consistent with those records in Your progress and final budget reports. You will submit copies of such records to the Foundation upon request.

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		[***]	$ 11,453,099
	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
[***]	[***]	[***]		
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[***]	[***]	[***]		
			Total Grant Amount	**Up to $48,945,928**

GRANT AGREEMENT
Investment ID INV-026060
ATTACHMENT B
TERMS & CONDITIONS

This Agreement is subject to the following terms and conditions.

PROJECT SUPPORT

PROJECT DESCRIPTION AND CHARITABLE PURPOSE

The Foundation is awarding You this grant to carry out the project described in the Investment Document ("*Project*") in order to further the Charitable Purpose. The Foundation, in its discretion, may approve in writing any request by You to make non-material changes to the Investment Document.

MANAGEMENT OF FUNDS

USE OF FUNDS

You may not use funds provided under this Agreement *("Grant Funds")* for any purpose other than the Project. You may not use Grant Funds to reimburse any expenses You incurred prior to the Start Date. At the Foundation's request, You will repay any portion of Grant Funds and/or Income used or committed in material breach of this Agreement, as determined by the Foundation in its discretion.

INVESTMENT OF FUNDS

You must invest Grant Funds in highly liquid investments with the primary objective of preservation of principal (e.g., interest-bearing bank accounts or a registered money market mutual fund) so that the Grant Funds are available for the Project. Together with any progress or final reports required under this Agreement, You must report the amount of any currency conversion gains (or losses) and the amount of any interest or other income generated by the Grant Funds (collectively, "*Income*"). Any Income must be used for the Project.

SEGREGATION OF FUNDS

You must maintain Grant Funds in a physically separate bank account or a separate bookkeeping account maintained as part of Your financial records and dedicated to the Project.

GLOBAL ACCESS

GLOBAL ACCESS COMMITMENT
You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

HUMANITARIAN LICENSE
Subject to applicable laws and for the purpose of achieving Global Access, You grant the Foundation 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. “Essential Background Technology” means Background Technology that is: (a) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (b) either incorporated into a Funded Development or reasonably required to exercise the license to a Funded Development. You confirm that You have retained sufficient rights in the Funded Developments and Essential Background Technology to grant this license. You must ensure this license survives the assignment or transfer of Funded Developments or Essential Background Technology. On request, You must promptly make available the Funded Developments and Essential Background Technology to the Foundation for use solely under this license. If You demonstrate to the satisfaction of the Foundation that Global Access can best be achieved without this license, the Foundation and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION
Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by the Foundation, You will seek prompt Publication of any Funded Developments consisting of data and results. “Publication” means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, You agree to adhere to the Foundation’s Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

INTELLECTUAL PROPERTY REPORTING
During the term of this Agreement and for 5 years after, You will submit upon request annual intellectual property reports relating to the Funded Developments, Background Technology, and any related agreements using the Foundation's templates or forms, which the Foundation may modify from time to time.

SUBGRANTS AND SUBCONTRACTS

SUBGRANTS AND SUBCONTRACTS
You may not make subgrants under this Agreement. You have the exclusive right to select subcontractors to assist with the Project.

RESPONSIBILITY FOR OTHERS
You are responsible for (a) all acts and omissions of any of Your trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the Project, and (b) ensuring their compliance with the terms of this Agreement.

PROHIBITED ACTIVITIES

ANTI-TERRORISM
You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY
You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

POLITICAL ACTIVITY AND ADVOCACY
You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You may not use Grant Funds to support lobbying activity or to otherwise support attempts to influence local, state, federal, or foreign legislation. Your strategies and activities, and any materials produced with Grant Funds, must comply with applicable local, state, federal, or foreign lobbying law. You agree to comply with lobbying, gift, and ethics rules applicable to the Project.

OTHER

PUBLICITY
A Party may publicly disclose information about the award of this grant, including the other Party's name, the total amount awarded, and a description of the Project, provided that a Party obtains prior written approval before using the other Party's name for promotional purposes or logo for any purpose. Any public disclosure by You or Your subgrantees, subcontractors, contingent workers, agents, or affiliates must be made in accordance with the Foundation's then-current brand guidelines, which are available at: www.gatesfoundation.org/brandguidelines.

LEGAL ENTITY AND AUTHORITY
You confirm that: (a) You are an entity duly organized or formed, qualified to do business, and in good standing under the laws of the jurisdiction in which You are organized or formed; (b) You are not an individual (i.e., a natural person) or a disregarded entity (e.g., a sole proprietor or sole-owner entity) under U.S. law; (c) You have the right to enter into and fully perform this Agreement; and (d) Your performance will not violate any agreement or obligation between You and any third party. You will notify the Foundation immediately if any of this changes during the term of this Agreement.

COMPLIANCE WITH LAWS
In carrying out the Project, You will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.

COMPLIANCE WITH REQUIREMENTS
You will conduct, control, manage, and monitor the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards ("*Requirements*"). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of Your annual progress report to the Foundation, You must report whether the Project activities were conducted in compliance with all Requirements.

If the Project involves:
a. any protected information (including personally identifiable, protected health, or third-party confidential), You will not disclose this information to the Foundation without obtaining the Foundation's prior written approval and all necessary consents to disclose such information;
b. children or vulnerable subjects, You will obtain any necessary consents and approvals unique to these subjects; and/or
c. any trial involving human subjects, You will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the Foundation in reviewing documents and providing input or funding does not modify Your responsibility for determining and complying with all Requirements for the Project.

RELIANCE
You acknowledge that the Foundation is relying on the information You provide in reports and during the course of any due diligence conducted prior to the Start Date and during the term of this Agreement. You represent that the Foundation may continue to rely on this information and on any additional information You provide regarding activities, progress, and Funded Developments.

INDEMNIFICATION
If the Project involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("*Indemnified Activities*"), You will indemnify, defend, and hold harmless the Foundation and its trustees, employees, and agents ("*Indemnified Parties*") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "*Claims*") arising out of or relating to the acts or omissions, actual or alleged, of You or Your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the Foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of Your governmental and sovereign immunities, if any.

INSURANCE
You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted industry standards and as required by law. You will ensure Your subgrantees and subcontractors maintain insurance coverage consistent with this section.

TERM AND TERMINATION

TERM
This Agreement commences on the Start Date and continues until the End Date, unless terminated earlier as provided in this Agreement. The Foundation, in its discretion, may approve in writing any request by You for a no-cost extension, including amending the End Date and adjusting any affected reporting requirements.

TERMINATION
The Foundation may modify, suspend, or discontinue any payment of Grant Funds or terminate this Agreement if: (a) the Foundation is not reasonably satisfied with Your progress on the Project; (b) there are significant changes to Your leadership or other factors that the Foundation reasonably believes may threaten the Project's success; (c) there is a change in Your control; (d) there is a change in Your tax status; or (e) You fail to comply with this Agreement.

RETURN OF FUNDS
Any Grant Funds, plus any Income, that have not been used for, or committed to, the Project upon expiration or termination of this Agreement, must be returned promptly to the Foundation.

MONITORING, REVIEW, AND AUDIT
The Foundation may monitor and review Your use of the Grant Funds, performance of the Project, and compliance with this Agreement, which may include onsite visits to assess Your organization's governance, management and operations, discuss Your program and finances, and review relevant financial and other records and materials. In addition, the Foundation may conduct audits, including onsite audits, at any time during the term of this Agreement, and within four years after Grant Funds have been fully spent. Any onsite visit or audit shall be conducted at the Foundation's expense, following prior written notice, during normal business hours, and no more than once during any 12-month period.

INTERNAL OR THIRD PARTY AUDIT
If during the term of this Agreement You are audited by your internal audit department or by a third party, You will provide the audit report to the Foundation upon request, including the management letter and a detailed plan for remedying any deficiencies observed ("*Remediation Plan*"). The Remediation Plan must include (a) details of actions You will take to correct any deficiencies observed, and (b) target dates for successful completion of the actions to correct the deficiencies.

RECORD KEEPING
You will maintain complete and accurate accounting records and copies of any reports submitted to the Foundation relating to the Project. You will retain such records and reports for 4 years after Grant Funds have been fully spent. At the Foundation's request, You will make such records and reports available to enable the Foundation to monitor and evaluate how Grant Funds have been used or committed.

SURVIVAL
A Party's obligations under this Agreement will be continuous and survive expiration or termination of this Agreement as expressly provided in this Agreement or otherwise required by law or intended by their nature.

GENERAL

ENTIRE AGREEMENT, CONFLICTS, AND AMENDMENTS
This Agreement contains the entire agreement of the Parties and supersedes all prior and contemporaneous agreements concerning its subject matter. If there is a conflict between this Agreement and the Investment Document this Agreement will prevail. Except as specifically permitted in this Agreement, no modification, amendment, or waiver of any provision of this Agreement will be effective unless in writing and signed by authorized representatives of both Parties.

NOTICES AND APPROVALS
Written notices, requests, and approvals under this Agreement must be delivered by mail or email to the other Party's primary contact specified on the Agreement Summary & Signature Page, or as otherwise directed by the other Party.

SEVERABILITY
Each provision of this Agreement must be interpreted in a way that is enforceable under applicable law. If any provision is held unenforceable, the rest of the Agreement will remain in effect.

ASSIGNMENT
You may not assign, or transfer by operation of law or court order, any of Your rights or obligations under this Agreement without the Foundation's prior written approval. This Agreement will bind and benefit any permitted successors and assigns.

COUNTERPARTS AND ELECTRONIC SIGNATURES
Except as may be prohibited by applicable law or regulation, this Agreement and any amendment may be signed in counterparts, by facsimile, PDF, or other electronic means, each of which will be deemed an original and all of which when taken together will constitute one agreement. Facsimile and electronic signatures will be binding for all purposes.

AMENDMENT 1
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant Agreement between the Bill & Melinda Gates Foundation and Daré Bioscience, Inc., effective June 30, 2021, and bearing Investment ID INV-026060
Amendment Purpose:	Reporting & Payment Schedule Change
"Amendment Date":	November 23, 2022

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone*, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Grant Agreement	[***]	July 2021	$ 11,453,099.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]	July 2022	$ 7,960,608.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		

[***]	[***]	[***]		
[***]	[***]	[***]		

[***]	[***]	[***]	November 2022	$ 4,436,204.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
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	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
	[***]	[***]		
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	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
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[***]	[***]	[***]		
[***]	[***]	[***]	[***]	Up to $[***]
	[***]	[***]		
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	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
Amended Total Grant Amount				**Up to $48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 2
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	September 14, 2023

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement	[***]	July 2021	$11,453,099.00
	[***]	[***]	July 2022	$7,960,608.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		

	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	November 2022	$4,436,204.00
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		
	[***]	[***]	September 2023	$4,500,000.00
	[***]	[***]		

	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		
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	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
Amended Total Grant Amount				**$48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 3
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	Date of this email

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		July 2021	$11,453,099.00
	[***]			
	[***]			
	[***]		July 2022	$ 7,960,608.00
	[***]			
	[***]			
	[***]			
[***]	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]			
	[***]		November 2022	$4,436,204.00

	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]		September 2023	$ 4,500,000.00
	[***]			
	[***]			
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[***]	[***]			
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[***]	[***]			
	[***]			
[***]	[***]	[***]	Scheduled: April 2024	$ 1,000,000.00
	[***]			
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[***]	[***]	[***]	[***]	[***]
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	[***]	[***]	[***]	[***]
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	[***]	[***]		
	[***]	[***]		
	[***]			
	[***]			
[***]	[***]			
Amended Total Grant Amount				**Up to $48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 4
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Bill & Melinda Gates Foundation and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	Date of this email

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement		July 2021	$11,453,099.00
	[***]			
	[***]			
	[***]		July 2022	$ 7,960,608.00
	[***]			
	[***]			
	[***]			
[***]	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]			
	[***]		November 2022	$4,436,204.00

	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]		September 2023	$ 4,500,000.00
	[***]			
	[***]			
	[***]			
[***]	[***]			
	[***]			
[***]	[***]			
	[***]			
	[***]		April 2024	$ 1,000,000.00
	[***]			
	[***]			
[***]	[***]		November 2024	$ 2,500,000.00
[***]	[***]	[***]	[***]	$[***]
	[***]			
	[***]			
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[***]	[***]	[***]		
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	[***]		[***]	$[***]
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[***]	[***]			
Amended Total Grant Amount				**Up to $48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 5
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Gates Foundation, formerly known as the Bill & Melinda Gates Foundation, and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	Payment & Reporting Schedule Change
"Amendment Date":	July 2, 2025

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement	[***]	July 2021	$11,453,099.00
	[***]	[***]	July 2022	$7,960,608.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
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[***]	[***]	[***]		

[***]	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	November 2022	$4,436,204.00
	[***]	[***]		
[***]	[***]	[***]	September 2023	$4,500,000.00
	[***]	[***]		
	[***]	[***]		
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	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	April 2024	$1,000,000.00
	[***]	[***]		

	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	November 2024	$2,500,000.00
[***]	[***]	[***]	July 2025	$6,000,000.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	October 2025	$4,000,000.00
	[***]	[***]		
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	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
			Amended Total Grant Amount	**$48,945,928.00**

As provided in the Agreement, signatures are not required.

AMENDMENT 6
to
GRANT AGREEMENT
Investment ID INV-026060

AMENDMENT SUMMARY PAGE

AMENDMENT INFORMATION	
Agreement to be Amended:	Grant agreement between the Gates Foundation, formerly known as the Bill & Melinda Gates Foundation, and Dare Bioscience, Inc., effective June 30, 2021, as amended, and bearing Investment ID INV-026060
Amendment Purpose:	No Cost Extension
"Amendment Date":	Date of this email
Amended "End Date":	The term of the Agreement is extended by changing the End Date to December 31, 2027

THIS AMENDMENT amends, and is made part of, the above-referenced Agreement and is effective as of the Amendment Date. Capitalized terms not defined in this Amendment will have the meaning provided in the Agreement. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect. In the event of a conflict between the Agreement and this Amendment, the terms of this Amendment will prevail.

REPORTING & PAYMENT SCHEDULE
This Amendment notifies You that the reporting and/or payment schedule for Your grant has changed. Your Reporting & Payment Schedule is deleted and replaced with the following:

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement	[***]	July 2021	$11,453,099.00
	[***]	[***]	July 2022	$7,960,608.00
	[***]	[***]		
	[***]	[***]		
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	[***]	[***]		

	[***]	[***]		
[***]	[***]	[***]		

[***]	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]	November 2022	$4,436,204.00
	[***]	[***]		
[***]	[***]	[***]	September 2023	$4,500,000.00
	[***]	[***]		
	[***]	[***]		
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	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	April 2024	$1,000,000.00
	[***]	[***]		

	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	November 2024	$2,500,000.00
[***]	[***]	[***]	July 2025	$6,000,000.00
	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]	October 2025	$4,000,000.00
	[***]	[***]		
	[***]	[***]	[***]	[***]
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	[***]	[***]		
	[***]	[***]		
	[***]	[***]		
[***]	[***]	[***]		
Amended Total Grant Amount				**$48,945,928.00**

As provided in the Agreement, signatures are not required.

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 Statement on Form S-1 (333-283280), the Registration Statements on Form S-3 (File Nos. 333-278380, 333-278378, 333-254862 and 333-238299) and the Registration Statements on Form S-8 (File Nos. 333-289607, 333-264020, 333-266699, 333-254864, 333-237473, 333-230802, 333-226904, 333-211697, 333-204007, and 333-198126) of Daré Bioscience, Inc. (the "Company") of our report dated March 26, 2026, relating to the consolidated financial statements as of December 31, 2025 and 2024 and for each of the years in the two-year period then ended (which includes an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern), which appear in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

Irvine, California
March 26, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Offering Statement of Daré Bioscience, Inc. (the "Company") on Form 1-A (File No. 024-12688) of our report dated March 26, 2026, relating to the consolidated financial statements as of December 31, 2025 and 2024 and for each of the years in the two-year period then ended (which includes an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern), which appear in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

Irvine, California
March 26, 2026

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 26, 2026

/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, 2025, 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 26, 2026

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